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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1351-1400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., December 21, 1945.

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS

1351. Misbranding of Doryl. U. S. v. Merck & Co., Inc. Plea of nolo contendere. Fine, \$15,000. (F. D. C. No. 11414. Sample Nos. 8475-F, 29923-F, 29926-F, 30384-F, 35242-F, 48851-F, 49311-F, 50487-F, 51266-F, 51571-F, 51618-F, 53252-F, 54015-F, 59510-F.)

The defendant prepared and sold a product under the name "Doryl" which consisted of ampuls containing a solution of 0.25 milligram of carbamylcholine chloride, dissolved in 1 cc. of water, intended for injection with a hypodermic needle. The defendant also prepared and sold under the same name the product involved in this case, which consisted of ampuls containing 0.15 gram of the same drug in powder form and which was 600 times the amount of the drug contained in the solution. The powder was intended for ophthalmologic use as eye drops. The ampuls of the solution and the powder had a generally similar appearance, the word "Doryl" being the most conspicuous word on both labels. A solution containing the powder, if injected, would be lethal.

On December 19, 1944, the grand jurors for the District of New Jersey returned an indictment against Merck & Co., Inc., Rahway, N. J., alleging shipment of a number of ampuls of Doryl between the approximate dates of December 18, 1941, and May 11, 1943, from the State of New Jersey into the States of Wisconsin, Missouri, California, Florida, Kentucky, Ohio, Pennsylvania, Massachusetts,

*For failure to bear an accurate statement of the quantity of the contents, see Nos. 1354, 1361, 1376, 1385, 1388, 1393; deceptive packaging, Nos. 1351, 1352, 1392; omission of, or unsatisfactory, ingredients statements, Nos. 1354, 1379, 1381, 1391; inconspicuousness of required label information, No. 1358; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1361; substitution of a drug, and its sale under the name of another drug, No. 1365; giving of a false guaranty, No. 1365; cosmetics, subject to the drug provisions of the Act, Nos. 1359, 1360, 1391, 1392.

North Carolina, and Michigan. The article was labeled in part: (Ampul) "0.15 Gm. * * * Doryl * * * (Carbamylcholine Chloride Merck)."

Examination showed that the article possessed the composition declared on its label.

The article was alleged to be misbranded (1) in that the labeling of the article was misleading since the boxes and cartons containing the ampuls and the ampul labels bore the statement "Do Not Use Intravenously," which suggested and implied that other methods of injection were safe and appropriate, whereas other methods of injection were not safe and appropriate, and the labeling of the article failed to reveal the fact, material in the light of such labeling, that the article was lethal when injected by any method; (2) in that the directions for use which appeared on the labeling of the article, "Do Not Use Intravenously" and "Sufficient to make 20 cc. of a 0.75% Solution for Ophthalmologic Use," were inadequate since they failed to reveal that the article was not to be used for injection by any method, but only in solutions for ophthalmologic use; (3) in that the labeling of the article failed to warn against injection other than intravenously; and (4) in that its container was so made, formed, and filled as to be misleading since the container was in a form in which drugs intended for injection are customarily packaged.

On February 2, 1945, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$1,000 on each of 15 counts in the indictment, a total fine of \$15,000.

1352. Misbranding of Doryl. U. S. v. 10 Ampuls of Doryl (and 3 other seizure actions against Doryl). Default decrees of condemnation and destruction. (F. D. C. Nos. 11498, 11501 to 11503, incl. Sample Nos. 51265-F, 51266-F, 51571-F, 51575-F.)

On December 27 and 28, 1943, the United States attorney for the District of Massachusetts filed libels against 19 ampuls of Doryl at Boston, Mass., and 4 ampuls of Doryl at Woburn, Mass., alleging that the article had been shipped by Merck & Co., Inc., from Rahway, N. J., between the approximate dates of March 11 and May 11, 1943. The article was labeled in part: "0.15 Gm. Ampul * * * Doryl (Carbamylcholine Chloride Merck) Do not use intravenously. * * * Sufficient to make 20 cc. of a 0.75% Solution for Ophthalmologic Use."

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since the statements in the labeling, "Do not use intravenously" and "for Ophthalmologic Use," were inadequate since they failed to reveal that the article was intended not to be used for injection, but only in solution for ophthalmologic purposes; (2) in that its labeling failed to bear adequate warnings since the labeling did not clearly warn that the preparation was not intended for injection and would be lethal if so used; (3) in that the statement "Do not use intravenously," appearing in the labeling of an article packaged in ampul form, was misleading since it suggested that the article was suitable for injection otherwise than intravenously, whereas the article, when injected, would cause death; and (4) in that its container was so made, formed, and filled as to be misleading since it was in a form in which drugs intended for injection are sometimes packaged.

On March 12, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1353. Misbranding of Salvitae, Salugen, and Syrup of Ambrozoin. U. S. v. American Apothecaries Co., Inc. Plea of guilty. Fine, \$400. (F. D. C. No. 6423. Sample Nos. 51112-E, 51114-E, 51115-E.)

On June 28, 1943, the United States attorney for the Eastern District of New York filed an information against the American Apothecaries Co., Inc., Long Island City, N. Y., alleging shipment of a quantity of the above-named products on or about March 10, 1941, from the State New York into the State of Massachusetts.

Analysis of a sample of the Salvitae disclosed that it consisted essentially of sodium sulfate, magnesium sulfate, sodium bicarbonate, compounds of lithium, potassium and sodium, and strontium, carbonates, citrates, tartrates, caffeine, and methenamine. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be an effective aid in the treatment of gingivitis, soft, bleeding gums, receding gums, and for conditions due to a deficiency in the alkalinity of the salivary secretions; that the article would augment, stimulate, and encourage the natural activity of the eliminative organs; that it would promote metabolism; that it

would aid individuals to remain physiologically correct; that it would aid metabolism to draw heavily upon the mineral elements for the neutralization of acid, maintenance of electrolyte concentrations of the body fluid, evolvment of bony tissue, and the sustentation of a proper physiology in individuals who, having given up an active life for a sedentary one, maintain or increase their food consumption but fail to expend resultant potential energy; that it would prevent tetany and parathyroid insufficiency by preventing the deprivation of calcium; that it would promote the concentration of magnesium and thereby prevent the development of muscular incoordination, convulsions, and death; that it would prevent lack of sufficient calcium and phosphorus and thereby prevent the restriction of the growth of bones and the production of osteoporosis of the long bones; that it would supply potassium and magnesium and thereby maintain osmotic pressure in both intracellular and extracellular fluids, the regulation of physiological neutrality, and a proper irritability of the heart muscles; that it would supply those minerals, the deficiency of which is the cause, in whole or in part, of rickets, prolonged postpartum invalidism, chronic asthenia, pellagra, and sprue; that it would prevent disturbance of the acid base equilibrium and the removal of a natural defense in the body against diabetes, gout, obesity, arthritis, and various infective disorders; that it was an efficient mineralizing and antacid measure; that it was a scientifically balanced combination of the salts of potassium, magnesium, calcium, strontium, sodium, and lithium, so quantitatively formulated as to provide the highest therapeutic efficiency; that it would aid in the elimination of waste products by accelerating the excretion of the uric acid in cases of gout, by promoting the oxidation of carbohydrates in cases of diabetes, and by raising the lowered metabolism that is responsible for obesity; that it would aid in discharging the toxic load of gout, diabetes, and obesity; that it would be insurance against the predisposition of systemic hyperacidity to the occurrence of rhinitis, grippe, influenza, bronchitis, and other infectious disorders of the upper respiratory tract; that it would be efficacious in the cure, mitigation, treatment, or prevention of acidity as evidenced by constipation, headaches, and biliousness; that it would replenish mineral deficiencies, act as a catalyzer for chemical reactions in processes of absorption, retention, and utilization, promote vigor of muscle and integrity of bone structure, enter into the intermediate metabolism of the endocrines, and sustain the alkalinity of the blood; that it would be efficacious in the prevention of acid intoxication and undue systemic acidity and the retention of toxic products which cause rheumatic pains, colds, headaches, undue nervousness, and chronic constipation; that it would remove from the urine all the end products of metabolism; that it would be efficacious in the cure, treatment, mitigation, or prevention of gastric hyperchlorhydria, cachexias, endocrine disturbances, and chronic atonic states; and that it would promote metabolism during pregnancy and following delivery, in the rachitis of childhood, in convalescence from exhausting diseases such as fever and pneumonia, and in invalidism. The article would not accomplish the results suggested and implied in its labeling. It was alleged to be misbranded further in that its label failed to bear adequate directions for use since the label failed to limit the duration for which the article might be taken; and in that its label failed to warn against the use of the article in cases of abdominal pain, nausea, vomiting, and other symptoms of appendicitis, and against frequent or continual use when such use might result in dependence upon cathartic drugs to move the bowels.

Analysis of a sample of the Salugen showed that it consisted essentially of boric acid, betanaphthol, compounds of aluminum, zinc and small proportions of thymol, eucalyptol and menthol, an alkaloid-bearing drug, flavoring material, and water. Bacteriological examination showed that the article was not antiseptic when diluted as recommended in the labeling. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article was a disinfectant; that, when used as a wet dressing, it would be efficacious in the treatment of abrasions, burns, chafing, chronic sores, cuts, insect bites, stings, and scalds; that it would be efficacious as a douche, gargle, and spray, and as an internal remedy in diarrhea, dysentery, and excessive intestinal fermentation; that it would be a general antiseptic and prophylactic; that it would help to destroy germ life, arrest hemorrhage, prevent suppuration, dispel wound feter, and promote healing without endangering human life or irritating delicate tissues; that, when used as a mouth wash or dentifrice, it would help prevent decay of teeth, invigorate the gums checkmate recession, and render the oral cavity germ-free; that it would be efficacious in the treatment of acute or chronic catarrhal affections of the nose, throat, or nasal passages, gonorrhea, leucorrhea, vaginitis, and diseases of the genito-

urinary tract, various eruptive affections of the skin, such as ivy poisoning, urticaria, eczema, impetigo, and prurigo, and accidental wounds, such as abrasions, cuts, and bruises; that it would help to prevent infection, diminish pain, and expedite repair; that it would be efficacious in the treatment of old sores, abscesses, ulcers, and suppurating wounds, and would stimulate granulation; that it would be efficacious in the treatment of fetid discharge from pus cavities and external wounds; that, when used as directed, it would be efficacious in the treatment of tonsillitis, laryngitis, pharyngitis, and sore throat, acute and chronic nasal catarrh, gingivitis of local or systemic origin, and spongy, bleeding, or receding gums; that the article would impart tone and firmness to the gums, would help prevent the decay of teeth, would normalize the salivary secretions, would prevent fermentative processes, and would tone the oral activity; and that it would be efficacious in preventing fetid breath and the spread of such contagious diseases as scarlet fever, smallpox, chickenpox, and measles, in disinfecting all discharges from a patient suffering from a contagious disease, in treating eruptive affections of the skin and an inflammatory condition of the skin caused by undue exposure to the sun, wind, or frost, in treating various intestinal disorders arising from the ingestion of unripe fruit, tainted meats or vegetables, sour or impure milk, or other unwholesome foodstuffs, and in treating intestinal fermentation involving diarrheal or dysenteric symptoms. The article would not accomplish the results suggested and implied in its labeling.

Analysis of a sample of the Syrup of Ambrozion disclosed that the article consisted essentially of terpene hydrate, guaiacol, ammonium chloride, compounds of sodium and potassium, a small proportion of alkaloid such as sanguinarine, sugar, and water. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the treatment of acute and chronic inflammatory affections of the upper respiratory passages where cough, labored breathing, lessened expectoration, and pain are disturbing factors; that it would aid in allaying respiratory hyper-sensitiveness; that it would overcome the feeling of tightness or suffocation by aiding the expulsion of mucous from the air passages, and would allay pain due to expulsive efforts; that it would be useful in acute and chronic bronchitis because it would increase the fluidity of bronchial secretions, stimulate expectoration, and exert a soothing influence on the bronchial mucous membrane; that it would tend to prevent the accumulation of mucous in the air passages of persons of advanced age suffering from chronic bronchitis, and thus render respiration less difficult or discomforting; that it could be used to distinct advantage as both a prophylactic and palliative in acute attacks of bronchitis, such as frequently follow exposure to cold or dampness; that it would be beneficial in the treatment of asthma; that, when used as soon as symptoms of an impending seizure of hay fever were experienced, it would be efficacious in preventing the development of an attack of hay fever; that it would be efficacious in cases of whooping cough, in diminishing the number and severity of paroxysms, in facilitating expectoration, and in tending to allay the nervousness of the patient; that it would render the patient less liable to attacks of vomiting after paroxysms of whooping cough, and would promote sleep; that the article would be advantageous in the prevention of attacks of cold, bronchitis, laryngitis, or other inflammatory affections of the respiratory tract in persons predisposed to such attacks; and that it would be efficacious in the cure, mitigation, treatment, or prevention of inflamed mucous membranes of the throat. The article would not accomplish the results suggested and implied in the labeling.

On October 11, 1944, the defendant having entered a plea of guilty, the court imposed a fine of \$100 on 1 count and \$150 on each of 2 other counts, a total fine of \$400.

1354. Misbranding of herb remedies. U. S. v. Alta C. Meskell. Plea of guilty. Fine, \$250. Sentence of 6 months' imprisonment suspended, and defendant placed on probation for 5 years. (F. D. C. No. 11417. Sample Nos. 17792-F, 17793-F, 33817-F to 33821-F, incl., 34014-F, 34015-F.)

On July 24, 1944, the United States attorney for the Middle District of Pennsylvania filed an information against Alta C. Meskell, Williamsport, Pa., alleging shipment on or about February 2 and April 18, 1943, from the State of Pennsylvania into the State of New York of a quantity of herb remedies referred to as No. 16-1, No. 21-01, Meskell's Special Compound No. 1-2-3, No. 120-00S Compound, No. 990 Laxative, No. 9990-B-T, No. 7, No. 1116, and No. 1321.

Analysis of the No. 16-1 showed that it consisted essentially of plant material including fennel seed, rosemary leaves, juniper berries, althaea root, sweet

fern leaves, malva leaves, black cohosh root, and podophyllum root. The article was alleged to be misbranded in that the statements on its labeling, "We can highly recommend it in case of Rheumatism. Sciatic Lumbago Cramps. Painful menses. Neuralgia, etc.," were false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of the conditions named, or the other conditions indicated by the abbreviation "etc."

Analysis of No. 21-01 showed that it consisted essentially of plant material including ground leaves and stem and rhizome tissues. The article was alleged to be misbranded in that the statements in its labeling, "Useful in Nervous Exhaustion and headaches and nervous depression * * * Distinguished for remedial power," were false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of nervous exhaustion, headaches, and nervous depression, and it was not "Distinguished for remedial power," i. e., it was not of outstanding value for its remedial properties.

The Meskell's Special Compound No. 1-2-3 consisted of a powder in a white box, "No. 1," a liquid, "No. 2," and a powder in a pink box, "No. 3." Analysis showed that the No. 1 powder consisted of Epsom salt; the No. 2 liquid consisted of cottonseed oil; and the No. 3 powder consisted of Rochelle salt. The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular entitled "Herbs are Healthful," and an accompanying leaflet entitled "Questionnaire Blank," which represented and suggested that the powders and liquid, when used singly or in combination with each other, would be efficacious in the cure, mitigation, treatment, or prevention of disorders of the liver, gallstones, pain below the ribs, at the stomach, and under the shoulder blades, nausea, belching of gas, spitting up of sour food, sallow complexion, distension of the stomach after eating, irregular bowels, ulceration of the stomach, dyspepsia, dizziness, colitis and enteritis, yellow complexion, sallow eyes, and coated tongue.

Analysis of the No. 120-00S Compound showed that it consisted of plant material including fennel seed, juniper berries, serpentaria root, wahoo bark, and wintergreen leaves. The article was alleged to be misbranded because of false and misleading statements in the aforesaid accompanying circular and leaflet regarding its efficacy in the cure, mitigation, treatment, or prevention of rheumatism, neuralgia, arthritis, and neuritis, and as an effective blood remedy.

Analysis of the No. 990 Laxative showed that it consisted of plant material including senna leaves, buckthorn bark, fennel seed, licorice root, cascara sagrada bark, calamus root, and ginger root. The article was alleged to be misbranded (1) because of false and misleading statements in the aforementioned circular and leaflet, which accompanied the article, regarding its efficacy in regulating the bowels, removing all superfluous bile from the liver, and strengthening the kidneys; (2) in that the labeling statements, "A combination of Native Pure Roots, Herbs, Barks and Flowers," were false and misleading since the article was not composed solely of native roots, herbs, barks, and flowers, but contained senna, a substance that is not native to the Western Hemisphere; and (3) in that its label failed to warn that the article should not be taken when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use of the article might result in dependence on laxatives to move the bowels.

Analysis of the No. 9990-B-T showed that it consisted essentially of plant material including thyme leaves, fennel seed, corn silk, uva ursi leaves, althaea root, cascara sagrada bark, ginger root, anise seed, and berberis root. The article was alleged to be misbranded because of false and misleading statements on its label regarding its efficacy as a tonic and in the toning of the digestive organism, and in the treatment of gastritis, bloating, and heartburn.

Analysis of the No. 7 showed that it consisted essentially of plant material including ginger root, sassafras bark, peppermint leaves, clove buds, sabal berries, juniper berries, cubeb berries, and cascara bark. The article was alleged to be misbranded (1) in that the statements, "No. 7 This will break a cold, la grippe or aching bones, neuralgia and nervousness. The herbs promptly destroys the cause of all these complaints," appearing in the aforementioned circular, which accompanied the article, were false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of colds, grippe, aching bones, neuralgia, or nervousness, and the article would not destroy the causes of those conditions promptly, or at all; and (2) in that the article was a laxative and its labeling failed to warn that the article should not be taken when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, or that frequent or continued use of the article might result in dependence on laxatives to move the bowels.

Analysis of No. 1116 showed that it consisted essentially of plant material including althaea root, mint leaves, sweet fern leaves, black cohosh root, and dog grass rhizomes. The article was alleged to be misbranded because of false and misleading statements on its label and in the afore-mentioned circular, which accompanied the article, regarding its efficacy in the cure, mitigation, treatment, or prevention of kidney and bladder irritation, diabetes, and Bright's disease, and as a remedy for either diabetes or Bright's disease.

Analysis of No. 1321 showed that it consisted essentially of plant material including buchu leaves, uva ursi leaves, equisetum, althaea root, and sassafras bark. The article was alleged to be misbranded because of false and misleading statements on the label and in the afore-mentioned circular, which accompanied the article, regarding its efficacy in the cure, mitigation, treatment, or prevention of kidney and bladder irritation, gravel, and backache, and in soothing inflammation and irritation of the kidneys or bladder.

The articles, with the exception of the Meskell's Special Compound No. 1-2-3, were alleged to be misbranded further in that their labels failed to bear any statements of the quantity of the contents.

The articles Compound No. 1-2-3, No. 120-00S, No. 990 Laxative, No. 9990-B-T, No. 7, No. 1116, and No. 1321 were alleged to be misbranded further because of false and misleading statements in the afore-mentioned circular accompanying them which represented and suggested that herbs were first in therapeutic importance with respect to harmlessness and effectiveness in combating all diseases; that all herbs were nonpoisonous; that the herb formulas for the articles were secret formulas and would be efficacious to heal most all diseases and to treat diseases considered to be hopeless cases; and that the herbs asparagus, bael, borage, balmony, bittersweet, bloodroot, blue flag, blue mallow, boneset, burdock, calamus, black cohosh, gravel root, goldenseal, ground ivy, wild thyme, and tolu balsam, either used alone or in combination, would purify the blood and would be efficacious in the cure, mitigation, treatment, or prevention of heart conditions, dropsy, diarrhea, affections of the chest, constipation, jaundice, kidney ailments, rheumatism, polypus, chest and lung conditions, bronchitis, blood and urine disorders, coughs, all fevers, liver disorders, dyspepsia, whooping cough, chronic catarrh, catarrh of the bronchial tubes, catarrh of the stomach, nervousness, neuritis, eczema, general debility, hardening of the arteries, goiter, and ulcers of the stomach.

The articles No. 16-1, No. 21-01, No. 990 Laxative, No. 1116, and No. 1321 were alleged to be further misbranded in that their labels failed to bear a statement of the common or usual name of each active ingredient since the statements "barks, herbs, roots and flowers" on the label of the No. 16-1, "roots, herbs, barks and flowers" on the labels of the No. 21-01 and the 990 Laxative, and "Herbs, Leaves, Barks, Roots, Flowers" on the label of the No. 1116, and "herbs, leaves, roots, barks and berries" on the label of the No. 1321, did not constitute statements of the active ingredients of the articles.

On October 18, 1944, a plea of guilty having been entered, the defendant was fined \$250 on count 1, and a sentence of 6 months in jail on the remaining 8 counts, to be served concurrently, was imposed. The jail sentence was suspended and the defendant was placed on probation for 5 years, with the understanding that she should discontinue selling misbranded drugs.

1355. Misbranding of Pal-Pinto Minerals. U. S. v. Texas Carlsbad Water Co. Plea of nolo contendere. Fine, \$100. (F. D. C. No. 11328. Sample No. 8900-F.)

On March 17, 1944, the United States attorney for the Northern District of Texas filed an information against the Texas Carlsbad Water Co., a corporation, at Dallas, Tex., alleging shipment of a quantity of the above-named product on or about May 7, 1943, from the State of Texas into the State of Mississippi.

Analysis of a sample of the article showed that it consisted essentially of sodium sulfate and sodium chloride with small proportions of magnesium sulfate and potassium chloride.

The article was alleged to be misbranded because of false and misleading statements in an accompanying circular entitled "Pal-Pinto Minerals," which represented and suggested that the article would be efficacious for many ailments due to a sluggish or poorly active system; that it would relieve inorganic aches and pains and a tired, "all in" feeling; that it would aid the user to function with the precision needed for an uninterrupted flow of energy and vitality; that it would remove the cause of illness and build up body resistance; that it would aid the kidneys in eliminating waste and impurities from the body, and would supply the system with the body minerals necessary to maintain good health and

overcome chronic ailments; that it would restore the kidneys, liver, and other organs to normal; that it would be efficacious in the treatment of rheumatism, kidney and liver sluggishness, neuritis, gallbladder troubles, hyperacidity, complexion troubles, and auto-intoxication; and that it would remove the cause of teeth or tonsil infection. The article would not be efficacious for such purposes.

It was alleged to be misbranded further (1) in that it was a laxative and its labeling failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence on laxatives; and (2) in that its labeling was misleading since it failed to reveal the fact that the article was essentially a laxative mixture of sodium sulfate and table salt with a small proportion of Epsom salt, which fact was material in view of the following representations borne on the labels: "Active Ingredients Magnesium 0.87% Sodium 32.13% Potassium 1.20% Carbonate 0.23% Sulphate 45.80% Chloride 18.96% Silica 0.01% Calcium Trace Iron Oxide Trace Aluminum Oxide Trace."

On September 26, 1944, a plea of *nolo contendere* having been entered, the defendant was fined \$100.

1356. Alleged misbranding of Willard's Tablets. U. S. v. 265 Packages and 258 Packages of Willard's Tablets, and 450 Envelopes of Printed Matter. Tried to the court. Judgment for claimant. Decree ordering dismissal of the libel and release of the goods. Judgment affirmed on appeal to the circuit court of appeals. (F. D. C. No. 8607. Sample Nos. 4011-F, 4066-F.)

On November 5, 1942, the United States attorney for the Southern District of Indiana filed a libel against 265 100-tablet packages and 258 15-tablet packages of Willard's Tablets, and against approximately 450 envelopes bearing the designation "Willard's Message," each envelope containing a circular letter entitled "A Healthy Stomach—A Happy Life" and leaflets entitled "Willard's Message to Acid Stomach Sufferers" and "The Willard Treatment used from Coast to Coast." It was alleged in the libel that the tablets had been shipped between the approximate dates of January 9 and October 9, 1942, by the Willard Tablet Co., from Chicago, Ill., and that the envelopes and contents were received by the consignee at Indianapolis, Ind., at or about the same time that each of the shipments of the tablets was received. On February 25, 1943, an amended libel was filed.

Examination of a sample of the article showed that each tablet contained approximately 10 grains each of bismuth subnitrate, sodium carbonate, and magnesium oxide, together with small amounts of pancreatin and peppermint oil.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use since the directions, "Take one tablet immediately after each meal, three times a day," provided for administration of the article at regular and stated intervals, whereas adequate directions would provide for administration only at such times as symptoms of excess acid in the stomach appeared.

It was alleged to be misbranded further in that certain statements on the cartons and bottles and on the envelope and contents accompanying the article were false and misleading since those statements created the impression that the tablets, when taken as directed, would be effective in the treatment and alleviation of stomach distress symptoms due to excess acid, stomach and duodenal ulcers, poor digestion, upset stomach, bad breath, sleeplessness, and jaded appetite, whereas the tablets, when taken as directed, would not be effective for such purposes.

On March 18, 1943, the Willard Tablet Co., claimant, filed its answer to the libel, denying the misbranding charges and alleging as an affirmative defense that the issue of the truth of the statements which were charged to be false and misleading had, therefore been finally determined by the Federal Trade Commission in favor of the claimant, and that the Commission's decision was *res judicata* on that issue.

On March 24, 1943, pursuant to agreement by the parties, a stipulation was filed with the court, setting forth the facts of the case as follows: That the claimant was the same company which was the respondent in the above-mentioned proceedings before the Commission; that the Commission on April 8, 1937, proceeded against the claimant by complaint, alleging unfair competition arising out of the advertising of the same "Willard's Tablets"; that the complaint charged, among other things, that the claimant falsely represented that the tablets constituted a competent and adequate cure or remedy for stomach and duodenal ulcers due to hyperacidity, and for poor digestion, acid dyspepsia, sour or upset stomach, gaseousness, bloating, heartburn, constipation, bad breath, sleeplessness, headaches, and jaded appetite, when such conditions were due to

or persisted because of excess acid; that an answer was filed by the claimant, denying such charges; that, after a hearing on the complaint, the Commission on October 15, 1938, ordered the claimant to cease and desist from representing, among other things, that the drug was a competent and adequate remedy or cure for ulcers which are due to or persist because of an excess acid condition, or that it would do more than neutralize excess acid and temporarily relieve the symptoms of distress due to such a condition, or that it would do more than provide relief from symptoms of distress caused by an excess acid condition and by ulcers which are due to or persist because of excess acid, unless such representation also stated that any benefit obtained other than such relief would be variable, depending upon the individual's reaction to the drug; that a modified cease and desist order was issued by the Commission on January 5, 1939, the modification made therein not being material in the instant libel action; that, as a result of such cease and desist order and in pursuance of the direction of the Commission, the claimant submitted to the Commission sample advertising matter to indicate compliance with such order; and that the representations which were claimed to constitute false and misleading statements under the Federal Food, Drug, and Cosmetic Act, were included in the sample advertising matter submitted to and approved by the Commission.

On June 4, 1943, the court adopted as special findings of fact the stipulation of the parties, and stated as a conclusion of law that the final order of the Federal Trade Commission between the same parties was *res judicata* of the issues in the libel action. On June 8, 1943, judgment was entered ordering the dismissal of the action and the release of the libelled property. Notice of appeal was filed by the government on August 4, 1943, and on March 7, 1944, the United States Circuit Court of Appeals for the Seventh Circuit handed down the following opinion, which affirmed the judgment of the district court:

MAJOR, *Circuit Judge*: "The United States (libellant) instituted this proceeding for condemnation of a quantity of Willard's Tablets shipped in interstate commerce on the ground that the labeling thereof was false, in violation of the Food, Drug and Cosmetic Act, 21 U. S. C. A. 352 (a), 352 (f), and the articles were therefore subject to seizure and confiscation (21 U. S. C. A. 334). The claimant filed an answer to the government's amended libel, setting up three affirmative defenses. The lower court sustained the claimant's defense of *res judicata*, based upon a prior proceeding before the Federal Trade Commission, and dismissed the action. From the order of dismissal, the government has appealed.

"The only question for decision is whether the proceedings before the Federal Trade Commission are *res judicata*, and, therefore, binding upon the District Court and determinative of the issues involved herein.

"The government urges as a basis for overruling the lower court's holding that: (1) the issues herein involved were not determined by the Federal Trade Commission; (2) unaffirmed decisions of the Federal Trade Commission do not have the finality necessary to constitute *res judicata*; (3) there is no mutuality of estoppel; (4) the lower court's holding would impair the enforcement of the Food, Drug and Cosmetic Act; and (5) the District Court improperly dismissed the amended libel as to that part alleging that the directions for use on the labeling were inadequate.

"The facts as stipulated and adopted by the lower court effectively dispose of the government's first contention. The stipulation discloses: (1) that the statements relied upon by the government to uphold the charge of misbranding are identical with those approved by the Federal Trade Commission; (2) that the fundamental issue of fact as to whether the Willard Tablets would give the relief claimed was considered by the Federal Trade Commission. We, therefore, have the incongruous situation of one branch of the government approving the method now pursued by the claimant and another branch seeking to condemn. This is, to say the least, placing claimant in an embarrassing situation and should be avoided if possible.

"In *George H. Lee Co. v. Federal Trade Commission*, 113 Fed. (2d) 583, the Circuit Court of Appeals for the Eighth Circuit upheld, and we think properly so, the defense of *res judicata*. Therein, the condemnation proceedings were instituted prior to the action before the Federal Trade Commission. The court on page 585 said:

Although the remedies sought by the government in the two proceedings were different—condemnation in the first, and a cease and desist order in the second,—it is obvious that the alleged falsity of the representations of the petitioner with respect to the therapeutic value and effectiveness of its product constituted the main basis for each of the proceedings * * *

And further, on page 586:

If the question of the falsity of the representations of the petitioner contained on its labels and circulars had been determined adversely to the petitioner in the libel proceeding, it could not have been heard to say in the proceedings instituted by the Commission that such representations were true. By the same token, the United States and its instrumentality, the Commission, were not, after the decree in the libel proceeding, entitled to say that the representations made by the petitioner which had been finally adjudged not to be false, were in fact false. The government had had its full day in court on that issue, had lost its case, and could not collaterally attack, either directly or indirectly, the decree entered against it.

And on page 585, the court stated:

Where the underlying issue in two suits is the same, the adjudication of the issue in the first suit is determinative of the same issue in the second suit.

"As was stated by the Supreme Court in *Sunshine Coal Co. v. Adkins*, 310 U. S. 381, 402:

A judgment is *res judicata* in a second action upon the same claim between the same parties or those in privity with them. *Cromwell v. County of Sac*, 94 U. S. 351. There is privity between officers of the same government so that a judgment in a suit between a party and a representative of the United States is *res judicata* in relitigation of the same issue between that party and another officer of the government. See *Tait v. Western Maryland Ry. Co.*, 289 U. S. 620.

"The government's second contention seems to rest solely upon the provisions of the Federal Trade Commission Act, as amended (15 U. S. C. A. 45 (b) (g)), that the Commission may, under certain conditions, modify its order after the expiration of time for appeal. Therefore, the contention is that such power of modification leaves an unappealed order without that finality essential to invoke the doctrine of *res judicata*. With this contention we do not agree.

"The Act provides that an order of the Commission shall become *final* at the expiration of sixty days if no appeal is taken (45 (g)), and further provides for heavy penalties for violation of such order (45 (1)). It further provides that "the findings of the Commission as to the facts, if supported by evidence, shall be conclusive." Thus, even the reviewing court in the same proceeding is bound by the findings of the Commission. To allow their finality to be attacked in a collateral proceeding would seem to run counter to the provisions and purposes of the Act. As was said in the case of *United States v. Piuma*, 40 Fed. Supp. 119, 122:

Is it the province of the court to try the truth or falsity of the defendant's advertisements already found to be false by the Commission? The answer to this question depends upon the meaning to be given the word 'final' as used in subsection (g). The purpose of the provision was to bring the doctrine of *res judicata* into the Federal Trade Commission's jurisprudence. * * * This court will not now retry that issue.

With this construction of the Act we agree. We must, therefore, uphold the decision of the lower court that the issues of fact tried by the Commission have a finality upon which *res judicata* may be predicated.

"We agree with appellee's contention that mutuality of estoppel is not herein involved. We have held that the facts found by the Federal Trade Commission are conclusive and binding upon the District Court. The same result would obtain if the government were depending upon these findings to sustain its charge of misbranding. The doctrine of *res judicata* is not dependent upon mutuality of estoppel by judgment, as is contended by the government. The cases cited in support of this contention are not applicable to the instant situation.

"What we have heretofore said sufficiently disposes of the argument that the decisions of the Federal Trade Commission should not be allowed to impair the enforcement of the Food, Drug and Cosmetic Act. Under the facts stipulated herein and to which this decision is limited, there can be no impairment of the enforcement of the aforementioned Act.

"The last contention of the government to be considered is that the plea of *res judicata* was directed to but one count of the libel and that it is entitled to a trial upon the other count, *i. e.*, upon the issue of whether the labels gave adequate direction for use. We are of the view that this contention is not tenable. As appears from the record, this case was submitted by both parties upon a stipulation of 'all of the facts.' The parties so understood it and so did the lower court. The suit was tried upon the issue of *res judicata* as to the whole libel, and the government's contention to the contrary comes too late.

"The judgment of the District Court is

AFFIRMED."

1357. Misbranding of Adolphus proprietary remedies. U. S. v. 359 Cartons of Broom Herb Laxative, 194 Boxes of Adolphus Peppermint, 8 Bottles of Calcium Pantothenate, 71 Bottles of Adolphus Natural Organic Calcium Tablets, 24 Bottles of Adolphus Brand Calcium Tablets, 60 Bottles of Adolphus Brand Soybean Lecithin, 104 Bottles of Adolphus Brand Wheat Germ Oil, 60 Bottles of Adolphus Brand Improved B Complex, 240 Bottles of Adolphus Brand Mineral Capsules, and 57 Bottles of Adolphus Brand Tar Shampoo. Default decree of condemnation and destruction. (F. D. C. No. 11598. Sample Nos. 55529-F, 55530-F, 55532-F to 55538-F, incl., 55540-F.)

On January 12, 1944, the United States attorney for the Southern District of California filed a libel against the above-mentioned products at Los Angeles, Calif. On January 18, 1944, an amendment to the libel was filed to cover a shipment of 4 boxes of booklets and leaflets at Los Angeles, Calif. It was alleged that the articles and the printed matter had been shipped on or about December 23, 1943, by Adolphus Hohensee, from Seattle, Wash.

The Broom Herb Laxative, also known as "Ozolax," was labeled in part: "Active All Herb Ingredients Senna Leaves, Buckthorn Bark, Licorice, Fennel Seeds, Blue Century Flowers, Peppermint." The article was alleged to be misbranded (1) in that certain statements in an accompanying booklet entitled "Adolphus Messenger of Health, Success and Happiness" regarding the efficacy of the article in building resistance against colds and sinus conditions and in keeping the system sweet and clean were false and misleading since the article would not be efficacious for such purposes; (2) in that its labeling failed to bear adequate directions for use since the article was an irritant laxative and the following of the directions in the booklet, which recommended that it be taken once a week for effective cleansing and that in cases of constipation it would be wise to use the article daily, might result in dependence upon laxatives to move the bowels; and (3) in that the common or usual name of each active ingredient was not placed on the label in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use, since the statement, "Active All Herb Ingredients: Senna Leaves, Buckthorn Bark, Licorice, Fennel Seeds, Blue Century Flowers, Peppermint," included not only the names of the laxative ingredients but also the names of ingredients which were not active for the reason that they did not contribute to the laxative effect of the article.

The peppermint was alleged to be misbranded in that certain statements in the accompanying booklets entitled "Nutritional Food Guide," "Adolphus Messenger of Health, Success and Happiness," and "The Health, Success and Happiness Lectures 'The Normal Ration'," were false and misleading since they represented and suggested that the article, when prepared as directed, would be efficacious as an alkalizer and would dissolve fat, whereas the article would not be effective for such purposes.

The calcium pantothenate was labeled in part: "Calcium Pantothenate with Vitamin B-1 Each Tablet Contains: 10 Mg. Calcium Pantothenate 333 USP Units Vitamin B-1 Plus B Complex Factors From Brewers' Yeast." The article was alleged to be misbranded in that certain statements on its label regarding its efficacy in preventing and correcting premature graying of the hair were false and misleading since the article would have no effect on the color of gray hair.

The calcium tablets designated as "Natural Organic Calcium Tablets" were labeled in part: "Each Tablet Contains Calcium—75 Milligrams Phosphorus—38 Milligrams Vitamin D—100 U. S. P. XI Units." The other lot of calcium tablets was labeled in part: "Adolphus Brand Calcium with Phosphorus and Vitamin D." Both lots were alleged to be misbranded in that certain statements in the accompanying booklet entitled "The Health, Success and Happiness Lectures Arthritis and Rheumatism" were false and misleading since they represented and suggested that the article would be efficacious in the prevention of arthritis, rapid aging due to lack of calcium, mental deficiency, stunted physical development, decayed teeth, acidity, nervousness, bad eyes, sleeplessness, lack of pep, neuralgia, numbness of the skin, dislike for exertion, and melancholia; that it would be efficacious in building bone, muscles, teeth, and perfect health; that it would aid the development of charm and magnetism, strengthen the mental powers, and improve the nutrition of nerve tissue, and especially heart tissue; that it would aid in the growth of hair; that it would act on the bone and brain; and that it would act as an agent of life and growth. The article would not be efficacious for such purposes. The "Natural Organic Calcium Tablets" were alleged to be further misbranded in that the statements in the labeling, "Calcium Tablets with Phosphorus," "As a dietary supplement take two tablets with each meal," "Each Tablet Contains Calcium—75 Milli-

grams Phosphorus—38 Milligrams," and "Four tablets three times daily will supply, with normal food intake, full adult requirements of Calcium & Phosphorus," were false and misleading since the article contained approximately 6 milligrams of calcium and 5 milligrams of phosphorus; four tablets three times daily would not supply full adult requirements of calcium and phosphorus; and the article would not supply, when taken in accordance with the directions on the package, a significant amount of either calcium or phosphorus.

The soybean lecithin was labeled in part: "4 Grains Soybean Lecithin in 3 Minimum Soybean Oil with 150 U. S. P. Units Vitamin D, from Irradiated Ergosterol." The article was alleged to be misbranded in that the statement, "The ideal nerve and brain food," which appeared in the accompanying booklet entitled "Nutritional Food Guide" and the accompanying order blank, was false and misleading since the article was not an ideal nerve and brain food.

The wheat germ oil was alleged to be misbranded in that the accompanying booklet entitled "Nutritional Food Guide" contained the following false and misleading statements: "Muscles * * * Lack of 'E'—Weakness; partial paralysis," and "Results of Mild Deficiency * * * 'E' Sterility disturbance during pregnancy, impaired mentality." The article would not be effective in the prevention of the diseases, conditions, and symptoms stated and implied.

The Improved B Complex Food Supplement was alleged to be misbranded in that certain statements in the accompanying booklets entitled "Adolphus Messenger of Health, Success and Happiness" and "Nutritional Food Guide" were false and misleading since they represented and suggested that the article would be efficacious in the prevention of indigestion, poor appetite, fatigue, lack of energy and pep, loss of weight, nervousness, inability to concentrate, difficulty in relaxing, dry scalp skin, slow heart beat, disease of the muscular substance of the heart, poor lactation, poor appetite, poor flow of digestive juices, constipation, tendency to peptic ulcers, bone marrow degeneration, loss of muscular tone, soreness and pain, spasms, general weakness, nervousness, neuritis, and gastric and intestinal disturbances; and that it would be efficacious in the promotion of perfect coordination, growth, healthy eyes, and normal skin and morale. The article would not be efficacious for such purposes.

The Adolphus Brand Mineral Capsules were alleged to be misbranded in that the statement in an accompanying order blank, "Adolphus Mineral Capsules * * * containing all the principal minerals needed in the human body," was false and misleading since the article, when taken in accordance with the directions in the labeling, would not supply all of the principal minerals needed in the human body, and since the amounts of calcium and phosphorus, two of the principal minerals needed, which would be supplied by the article when taken in accordance with the directions, were but a small fraction of the amounts needed.

The Adolphus Brand Tar Shampoo was alleged to be misbranded in that the statement on the order blank, "Adolphus Tar Shampoo For * * * dandruff, and falling hair," was false and misleading since the article was not an adequate remedy for dandruff and falling hair.

The articles, with the exceptions of the tar shampoo and the Broom Herb Laxative, were alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7924.

On April 14, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1358. Misbranding of Udga Tablets. U. S. v. 62 Boxes, 3 Bottles, and 6 Bottles of Udga Tablets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 6912. Sample No. 86830-E.)

On February 27, 1942, the United States attorney for the Northern District of Illinois filed a libel against 62 boxes, each containing 20 tablets, 3 bottles, each containing 100 tablets, and 6 bottles, each containing 50 tablets, of the above-named product at Chicago, Ill., alleging that the article had been shipped from St. Paul, Minn., by Udga, Inc., on or about January 8, 1942.

Analysis showed that the article contained, per tablet, 6.88 grains of bismuth subcarbonate, 10.23 grains of magnesium oxide, 7.29 grains of sodium bicarbonate, 0.2 grain of Rochelle salt, and a small proportion of saccharine. The statement of active ingredients was in small, inconspicuous type.

The article was alleged to be misbranded in that certain statements on its label and in an accompanying circular were false and misleading since they represented and suggested that the article would be efficacious for the relief of excessive gastric hyperacidity as manifested by sour stomach, heartburn, acid dyspepsia, excessive gas, belching, and flatulence; and that it would be efficacious

for the relief of persons suffering from stomach ailments caused by improper diet, irregular eating habits, consuming too many acid-producing foods, or over-eating. The article would not be efficacious for such conditions.

The article was alleged to be misbranded further (1) in that the statement of active ingredients, "contain: Bismuth Subcarbonate; Magnesium Oxide; Sodium Bicarbonate; Saccharine; Rochelle Salt," appearing on the box label of the article, was not prominently placed thereon with such conspicuousness as to render it likely to be read under customary conditions of purchase and use; (2) in that its labeling failed to bear adequate directions for use since the directions did not provide a limitation as to duration of use; and (3) in that its labeling did not bear a warning that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence on laxatives.

On April 4, 1945, Udga, Inc., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1359. Adulteration and misbranding of Pso-Ridisal. U. S. v. 38 Packages and 83 Gross of Pso-Ridisal. Consent decrees of condemnation. Product ordered released under bond. (F. D. C. Nos. 6679, 11683. Sample Nos. 86401-E, 66407-F, 66408-F, 66443-F.)

On or about January 17 and 28, 1944, the United States attorneys for the Northern District of Illinois and the Western District of Missouri filed libels against 38 packages of Pso-Ridisal at Chicago, Ill., and 83 gross of the same product at Kansas City, Mo., alleging that the article had been shipped from Royal Oak, Mich., by the Nu-Basic Products Co., between the approximate dates of November 19, 1941, and December 15, 1943. The libels against the Missouri and Illinois lots were amended on or about February 14 and 23, 1944, respectively.

Analysis of samples disclosed that the article consisted essentially of sulfanilamide, mineral oil, glycerin, small proportions of carbolie acid, and soap and water.

The article was alleged to be misbranded in that certain statements appearing in the labeling of each lot regarding the efficacy of the article in the treatment of psoriasis, and certain additional statements in the labeling of the Missouri lot regarding the efficacy of the article in the treatment of skin diseases, including athlete's foot, dandruff, eczema, acne, diaper rash, and industrial dermatitis, were false and misleading since the article would not be efficacious in the treatment of the conditions mentioned.

The article was alleged to be misbranded further in that its labeling failed to bear adequate warnings, since the article contained sulfanilamide and its labeling failed to warn that its use should be discontinued if a new skin rash appeared or if the skin condition under treatment became worse.

The article in the Illinois lot was alleged to be adulterated in that its strength differed from that which it was represented to possess since its labeling represented that each fluid ounce contained $\frac{3}{8}$ grain of sulfanilamide, whereas each fluid ounce contained 6.7 grains of sulfanilamide.

On June 30, 1942, the Nu-Basic Products Co. having appeared as claimant for the Illinois lot and having requested that the case be removed for trial to the United States District Court for the Eastern District of Michigan on the ground that that district was in reasonable proximity to the claimant's principal place of business, the court, after due consideration, entered an order denying the claimant's request for a change of venue. Thereafter, the Nu-Basic Products Co. appeared as claimant in the case of the Missouri lot and, pursuant to a motion filed by the claimant, an order was entered on April 11, 1944, providing for the removal of the case to the Northern District of Illinois. On April 12 and 26, 1944, the claimant having admitted the facts of the libels, judgments of condemnation were entered in each case and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1360. Misbranding of Sulfa-Seb and Sulfa-Ped. U. S. v. 50% Dozen Bottles of Sulfa-Seb and 17% Dozen Bottles of Sulfa-Ped. Tried to the court. Judgment for the Government. Decree ordering the condemnation and destruction of the labeling and the release of the product to the claimant. (F. D. C. No. 11075. Sample Nos. 3933-F, 3934-F.)

On or about November 10, 1943, the United States attorney for the Western District of Missouri filed a libel against 50% dozen bottles of Sulfa-Seb and 17% dozen bottles of Sulfa-Ped at Kansas City, Mo. On February 14, 1944, an amended libel was filed. It was alleged that the articles had been shipped on

or about October 19, 1943, from Royal Oak, Mich., by the Nu-Basic Products Co.; and charged that they were misbranded. The misbranding charges appear in the opinion *infra*.

Examination of samples disclosed that each of the articles contained approximately $\frac{1}{2}$ gram of sulfanilamide per fluid ounce, approximately 0.75 gram of phenol (carbolic acid) per 100 cc., oil, including a large proportion of mineral oil, and water.

On March 27, 1944, the Nu-Basic Products Co., claimant, having filed an answer denying that the products were misbranded as alleged in the libel, the case came on for trial before the court without a jury. The trial was concluded on March 29, 1944, and on April 3, 1944, the court handed down the following memorandum opinion and findings of fact and conclusion of law:

OTIS, *District Judge*: "The amended information in libel in this proceeding was filed February 14, 1944. It makes reference to two preparations, one known as 'Sulfa-Seb,' the other as 'Sulfa-Ped.' The charge is that these preparations are misbranded within the meaning of Title 21, U. S. C., Section 352. That section provides *inter alia* that a drug 'shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular' and that it 'shall be deemed to be misbranded (f) unless its labeling bears . . . such adequate warnings . . . against unsafe dosage or methods . . . of administration or application, in such manner and form, as are necessary for the protection of users; . . .'

"The information charges that the labeling of the preparation known as 'Sulfa-Seb,' which reads, in part, 'For hair and scalp . . . Designed as a fungicide to relieve itching, and treat and control the condition resulting from infection round the follicles of the hair,' is false and misleading in the following respects: that the article (1) is not an adequate treatment for disease conditions of the hair and scalp; (2) that it is not fungicidal; and (3) that it will not control conditions resulting from infection around the follicles of the hair.

"The information charges that the labeling of the preparation known as 'Sulfa-Ped,' which reads, in part, 'A new treatment for Athletes Foot . . . Designed as a fungicide to relieve discomfort and treat and control the conditions identified with fungus and bacterial conditions of the feet . . .,' is false and misleading in that the preparation is (1) not a treatment for athlete's foot; (2) is not a fungicide; and (3) will not relieve discomfort and treat and control conditions identified with fungus and bacterial conditions of the feet.

"The information alleges that both preparations are misbranded for that the labels contain no such adequate warnings 'as are necessary for the protection of users since the articles contain sulfanilamide' and no warnings that 'their use [i. e. of the preparations] should be discontinued if a new skin rash appears or if the skin condition under treatment becomes worse.'

"We begin this memorandum by first discussing the first charge in the information, that the preparation known as 'Sulfa-Seb' is false and misleading in the respects indicated in the information.

"1. There has been no real controversy in the case between counsel for plaintiff and counsel for claimant touching the applicable law. The language of the statute is clear enough. If the labeling 'is false and misleading in any particular' the preparation bearing the label has been misbranded. Obviously it is necessary first of all to determine *what* representation is made by the label and to determine whether *that* representation is false and misleading in any particular. It would seem to be obvious, moreover, that in determining whether the representation on a label is false and misleading in any particular *all* the language of the label must be considered. None would contend that single words or phrases should be lifted out and that if those words or phrases separately considered can be found to be untrue, then the preparation should be condemned as misbranded. Single words or phrases might be so explained by other language as that there is no misrepresentation whatever. Fairness requires that the whole legend upon the label of 'Sulfa-Seb' should be set out so that the label may be considered as a whole. Accordingly, we do set out the label by inserting at this point one of the labels:

A SULFA-DRUG COMPOUND SULFA-SEB A Nu-Basic [design] Product FOR HAIR AND SCALP A proprietary compound of mineral and vegetable oils which acts as a carrying agent for Sulfanilamide, the active medicant. Designed as a fungicide to relieve itching, and treat and control the condition resulting from infection round the follicles of the hair. ACTIVE MEDICANT SULFANILAMIDE $\frac{1}{2}$ GRAM TO EA. FL. OZ. Distributed by SULFA PRODUCTS CO., 1125 Grand Ave. Kansas City, Mo. SHAKE WELL BEFORE APPLYING ALSO CONTAINS Phenol (less than 1% by volume) and other inert ingredients in varying amounts. GUARANTEE Return for refund must be made within 2 weeks of purchase. EXTERNAL USE ONLY SHAKE WELL BEFORE APPLYING Directions for Use Massage

thoroughly into scalp. Comb out loosened scale using fine tooth comb. Use often as necessary to keep scalp moist with preparation. If hair is left too oily from treatment, remove excess oil by brushing. Set and groom with wetted comb. Wash hair no oftener than once a week. Content 4 Fluid Ounces \$2.50. EXTERNAL USE ONLY. MFG. BY—SULFA PRODUCTS COMPANY OF AMERICA—DIV. NU-BASIC PROD. CO., ROYAL OAK, MICH.

"Any one who inspects this label will at once discern that it contains much language which is not charged as being false or misleading and which obviously is not false or misleading. Some of the language is devoted to precise directions as to how the preparation is to be used. Some of it is a guarantee of return of money. A part of it is a warning that the preparation is 'for external use only.' Some of it describes accurately all of the ingredients in the preparation. Much of that part of the legend which is the object of the government's complaint is in type so small that it would almost certainly escape being read by any ordinary purchaser. The most prominent part of the label is the name of the preparation, 'Sulfa-Seb,' a name which certainly means nothing and conveys no significance. In somewhat smaller type, and yet in legible type as distinguished from the minute wording of the rest of the label, are the words 'FOR HAIR AND SCALP.' Here is the real representation which is made to the purchasing public. Nine out of ten of the purchasers of this preparation in all probability would read no other part of the label than the words in conspicuous letters 'FOR HAIR AND SCALP.' (What advertising, what circular, what verbal recommendations may have influenced purchasers we do not know but very reasonably we may conclude that an intention to purchase was formed *before* the label was read). Let us then first consider whether the 'FOR HAIR AND SCALP' is false and misleading.

"We agree at once with the contention of the Government in this case that there is an implication in the words 'FOR HAIR AND SCALP' which constitutes a part of the meaning to the ordinary observer and purchaser. By the use of these words it is represented that the preparation, when applied externally and in the manner prescribed by the directions on the label, is *beneficial* to the hair and scalp, that the use of the preparation will promote the health of hair and scalp. To say, however, that the words 'FOR HAIR AND SCALP' alone (as was said in the argument by learned counsel for the Government) would mean to an ordinary observer that the preparation was a *panacea* for every possible disease that might attack the hair or scalp seems to us grossly to distort the meaning which the reader would derive from the language employed. The reasonable interpretation of the words, considered alone, is that the use of the preparation in the manner directed will benefit the hair and scalp when affected by such commonly known maladies as those causing, for example, dandruff, falling hair, threatening baldness.

"When we descend from the words in large type, 'FOR HAIR AND SCALP,' into the legend minutely printed beneath them, we are given the more specific information that the preparation is 'Designed as a fungicide to relieve itching' and that is it 'Designed as a fungicide to treat and control the condition resulting from infection round the follicles of the hair.' Here the words that would mean anything to the ordinary reader and observer (the word 'fungicide' would mean nothing except to the rare individual) are the words to 'relieve itching' and the words 'to treat and control the condition resulting from infection around the follicles of the hair.'

"The impression then created by this label on the ordinary purchaser and observer, if he reads only the conspicuous words, is that here is a preparation that will be helpful in dealing with such common maladies as dandruff, falling hair, etc., and, if he descends into the minute type, that here is a preparation that will relieve itching in the scalp and that will beneficially affect a condition resulting from infection in the scalp.

"With such an interpretation placed upon the label, and we believe it is a fair interpretation, not a far fetched and distorted one, the question is, is this preparation one which will benefit the hair and the scalp with respect to the common maladies referred to and is it a preparation which will relieve itching in the scalp and will benefit conditions resulting from infection in the hair. If the preparation will do these things it certainly cannot justly be condemned as falsely labeled.

"2. The evidence in the case was of two general classes, the testimony of experts and the testimony of laymen. The testimony of the laymen called by the Government (there were only a half dozen of these) chiefly related to the charge of misbranding for failure to warn of dangers. It did not particularly bear upon the charge which we now are especially considering, namely, was the label of 'Sulfa-Seb' false and misleading. The testimony of the laymen who testified for the claimants (there were fifteen of these) did directly bear upon this charge, either as against 'Sulfa-Seb' or 'Sulfa-Ped.' But the testimony of a few

laymen, however honest that testimony may be (and we regard the testimony of each of the laymen appearing in this case as entirely honest) is of slight value upon the issue under present discussion. There were many thousands of users of these preparations. The evidence indicated that there were hundreds of users even in Kansas City. That a small number experienced unsatisfactory results, which they ascribed to some deficiency or injurious element in the preparation, and that a small number experienced satisfactory results which they ascribed to the preparation, is of small significance. The nature of the simplest disease is so obscure to a layman that his conclusions touching what will benefit it and what will not benefit it mean little. We would not say, of course, that if we were dealing with and had the results of tens of thousands of cases, we would not have something significant. A few dozen instances are of such trifling value as that they can almost entirely be disregarded.

"The scientific testimony in a case of this character is the testimony that counts. Scientific testimony is available to support any meritorious cause, even, as we know, when the leading physician in a community or the American Medical Association itself is under attack. Of course, scientific testimony is available to the Government in support of any meritorious cause presented by the Government. The Government has its official staff of scientists of outstanding ability and the government is able to obtain the services of other scientists of outstanding ability. But private individuals also are able to obtain the testimony of outstanding men of science *provided there is real merit in their cause*. Claimants in this case had the financial ability to obtain testimony. But they put only one so-called expert (we use the word 'so-called' advisedly) on the stand. They brought him from San Antonio, Texas, to Kansas City and paid him, according to his testimony, at the rate of \$100 a day and, we suppose, his expenses also. (We judge that was the zenith of his professional earnings to the present date.)

"The testimony of the young M. D. brought by claimants from Texas was pitifully weak. His qualifications were unsatisfactory, his experience in the practice of medicine was brief and limited, his knowledge of the science of the subject under inquiry was obviously slight. He could say 'Yes' to leading questions, but if he had been asked to discuss the sciences involved he would have floundered hopelessly. He was spared, if not by merciful counsel (who also were floundering) at least by a merciful court.

"There was a reason for the complete failure of the claimants to support their contentions by outstanding expert testimony. That testimony just was not procurable. The failure of the claimants in this respect impressed us as almost the equivalent of a confession of the general accuracy of the testimony of the Government's experts. The general effect of that testimony was that while the preparation 'Sulfa-Seb' might have some slight temporary value in some instances by way of relieving an itching scalp or by way of temporarily removing dandruff, it had no real value with respect to any malady of the scalp, whether generally and commonly known or obscure in character and difficult to diagnose. The general effect of the testimony of the experts for the Government, whose qualifications were outstanding, was certainly to the effect that the preparation known as 'Sulfa-Seb' constituted no kind of a treatment or control for infection in the scalp and round the follicles of the hair. We are bound to say that the effect of the scientific testimony offered by the Government was overwhelming *as against the complete emptiness of the scientific testimony offered by the claimant*.

"3. Much of what we have said concerning the preparation known as 'Sulfa-Seb' is equally applicable to the preparation known as 'Sulfa-Ped.' We set out here the exact label of 'Sulfa-Ped' which the Government has attacked. There cannot be any objection to much of this label. Most of it is entirely true and accurate. But we have reached the conclusion that there is some exaggeration in the label in that part of the legend in which it is represented that the preparation is a beneficial treatment and a control for 'the conditions identified with fungus and bacterial conditions of the feet.'

A SULFA DRUG COMPOUND SULFA-PED A NEW TREATMENT FOR ATHLETE'S FOOT S P A nu-Basic Product. A proprietary compound of mineral and vegetable oils which acts as a carrying agent for Sulfanilamide, the active medicant. Designed as a fungicide to relieve discomfort and treat and control the conditions identified with fungus and bacterial conditions of the feet. ACTIVE MEDICANT SULFANILAMIDE ½ Gram To EA. FL. OZ. SHAKE WELL BEFORE APPLYING Also Contains Phenol (less than 1% by volume) and other inert ingredients in varying amounts. GUARANTEE Return for refund must be made within 2 weeks of purchase. EXTERNAL USE ONLY SHAKE WELL BEFORE APPLYING Directions for use. Chronic Cases: Massage well into affected parts, morning and night. Take daily foot bath in warm water before applying night application. Use only mild soap. Acute Cases: Puncture blebs and permit fluid to drain out. Bathe in warm water using mild soap. Dry thoroughly. Apply and cover

with white cotton hose. Use new footwear. CONTENTS: 4 FL. OZS. \$2.50 EXTERNAL USE ONLY Distributed by SULFA PRODUCTS CO. 1125 GRAND AVE. KANSAS CITY, MO. MFG. BY—SULFA PRODUCTS COMPANY OF AMERICA—DIV. NU-BASIC PROD. CO. ROYAL OAK, MICH.

CERTAIN MATTERS OF EVIDENCE

"4. During the trial of the case there was offered in evidence by claimants a large number of letters (responses received from purportedly satisfied customers to questionnaires mailed out by claimants). We refused to receive these letters in evidence for reasons which were stated at the time of the ruling. Such letters are so obviously hearsay that the matter of the propriety of the ruling does not seem to us to be at all debatable. No question of the good faith of the manufacturers or of the claimants is involved in this proceeding. The proceeding is not brought against individuals. The proceeding is against inanimate preparations. The preparations, not individuals, are attacked. There is no reason to question the good faith of any one in this proceeding. We believe the claimants did act in good faith. The only question in the case is, are the labels on the bottles false and misleading in the sense that the information conveyed by them to ordinary readers is erroneous.

"Another matter of evidence, which was taken under submission, is made up of a number of exhibits, being claimants' Exhibits 14 to 21, inclusive. Objection was made by the Government to the reception of these exhibits. The exhibits were scientific treatises, each of which discusses the particular preparation involved in this proceeding. It seems clear to us that these exhibits were not competent in evidence. The reasons for that conclusion are elementary. Undoubtedly in the cross examination of an expert witness he may be asked whether he agrees or does not agree with certain statements contained in reputable treatises. There is no convincing authority, however, for the view advanced by learned counsel for the claimants in this case, to-wit, that *as affirmative proof* treatises may be offered in evidence. If the testimony of Dr. X, for example, is desired by a party, he can call him as a witness so that he can be cross examined in court. If he is beyond the jurisdiction of the court, undoubtedly the party can take his deposition, when again he may be cross examined. But it is unthinkable that a party may have some witness (in this instance it was a layman) say that Dr. X is an authority in a certain field and then to offer in evidence some book or treatise which may have been written by Dr. X.

"Notwithstanding our views of the law in this regard are very clear, we have read all of the exhibits referred to which were offered in evidence by the claimants. *For the purpose of this case we overrule the objection to these exhibits.* Nothing contained in the exhibits affects the findings of fact which we shall hereafter make. Findings of fact are made as of the time when the information in libel was filed. What may have been the view of scientific men on dates earlier than that date, of course, is not controlling. The knowledge of scientists, especially in a field so new as that which deals with the sulfa-drugs, is a growing knowledge. The science is in the process of evolution. The best views of the ablest scientists two or three years ago may not be especially valuable now.

MATTER OF WARNINGS

"The charge of inadequate warnings upon the labels was an afterthought. The original information in libel did not contain that charge. We are satisfied that the evidence does not warrant condemnation of the preparations on account of failure to include warnings.

FINDINGS OF FACT

"1. The label 'Sulfa-Seb' is false and misleading in that it represents that the preparation labeled is a remedy effective as a treatment for the commonly known maladies affecting the scalp and hair, whereas its only value is in relieving an itching scalp and in temporarily, in some instances, removing dandruff, and it is false and misleading in that it represents that the preparation labeled is a treatment or control for infections in the scalp and round the follicles of the hair.

"2. The label 'Sulfa-Ped' is false and misleading in that it represents that the preparation labeled is a treatment of and will control the conditions identified with fungus and bacterial conditions of the feet.

"3. Neither the labels of 'Sulfa-Seb' or 'Sulfa-Ped' is misbranded in that it does not contain an appropriate warning of dangers incident to the use of the preparations.

CONCLUSION OF LAW

"The prayer of the amended information in libel should be granted. The labels on the preparation known as 'Sulfa-Seb' and 'Sulfa-Ped' seized by the marshal should be condemned. The false and misleading labels on such preparations should be destroyed."

On the same date, judgment was entered condemning and ordering the destruction of the labels of the products. It was further ordered that when the labels had been destroyed the products should be returned to the claimant for use in compliance with the law.

1361. Misbranding of citrate of magnesia. U. S. v. 200 Cases of Citrate of Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 11648. Sample No. 23693-F.)

On or about January 20, 1944, the United States attorney for the District of New Jersey filed a libel against 200 cases, each containing 24 bottles, of citrate of magnesia at Atlantic City, N. J., alleging that the article had been shipped on or about November 5, 1943, from Brooklyn, N. Y., by the National Magnesia Co.; and charging that it was misbranded. The labeling consisted of the words "Citrate of Magnesia" blown into the glass of the bottles, and the words "Citrate of Magnesia U. S. P." on the bottle cap.

The article was alleged to be misbranded (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents; (2) in that its labeling failed to bear adequate directions for use; and (3) in that its labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use of the preparation might result in dependence on laxatives.

On October 27, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that the contents of the bottles be destroyed and that the empty bottles be released to the consignee from whom the product was seized.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1362. Adulteration of sterile distilled water and dextrose solution. U. S. v. Winthrop Chemical Co., Inc. Plea of guilty. Fine, \$18,000. (F. D. C. No. 11420. Sample Nos. 6962-F, 6963-F, 20251-F, 20568-F, 20569-F, 23819-F, 39113-F, 45035-F, 51818-F, 52893-F, 53059-F.)

On May 25, 1944, the United States attorney for the Southern District of New York filed an information against the Winthrop Chemical Co., Inc., New York, N. Y., alleging shipment of quantities of the above-named products between the approximate dates of May 3 and August 6, 1943, from the State of New York into the States of Missouri, Connecticut, Rhode Island, Massachusetts, Virginia, Pennsylvania, and Illinois.

Examination disclosed that all shipments of the sterile distilled water contained pyrogens; that certain shipments of the article contained undissolved material; and that one shipment was contaminated with living micro-organisms. The United States Pharmacopoeia requires that water for injection, which the article purported to be, shall be sterile, free from pyrogens, and free from any turbidity or undissolved material.

Examination of the dextrose solution disclosed that it contained pyrogens and undissolved material, and that a portion also was contaminated with viable mold. The United States Pharmacopoeia requires that dextrose injection or dextrose ampuls, which the article purported to be, shall be sterile and free from pyrogens and undissolved material.

The articles were alleged to be adulterated in that the sterile distilled water purported to be water for injection and the dextrose solution purported to be dextrose injection or dextrose ampuls, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but the quality and purity of the articles fell below the standard set forth in that compendium; and the differences in quality and purity of the articles from the official standards were not plainly stated, or stated at all, on their labels. The articles were alleged to be adulterated further in that pyrogens and undissolved material had been mixed or packed with all lots of the articles, and mold had been mixed or packed with a portion of the dextrose solution, so as to reduce the quality of the articles.

On October 4, 1944, a plea of guilty having been entered on behalf of the corporation, the court imposed a fine of \$1,500 on each of the 12 counts in the information, a total fine of \$18,000.

1363. Adulteration and misbranding of Gestrone Chorionic Gonadotropin, and adulteration of chorionic gonadotropic hormone. U. S. v. Pro-Medico Laboratories, Inc., and Samuel Heller. Pleas of guilty. Corporate defendant fined \$750, and individual defendant sentenced to serve 3 months in jail. (F. D. C. No. 7745. Sample Nos. 54960-E, 54961-E, 77049-E.)

On June 29, 1943, the United States attorney for the Eastern District of New York filed an information against the Pro-Medico Laboratories, Inc., Brooklyn, N. Y., and Samuel Heller, president of the corporation, alleging shipment of quantities of the above-named products on or about April 28 and May 27, 1942, from the State of New York into the State of Pennsylvania.

The chorionic gonadotropic hormone and a portion of the Gestrone Chorionic Gonadotropin were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since the former was represented to possess in each cubic centimeter a physiological activity of 500 International Units of anterior pituitary-like sex hormone, and the latter was represented to contain in each cubic centimeter 100 International Units of anterior pituitary-like hormone, whereas the former possessed not more than 83.5 International Units and the latter not more than 17.2 International Units of anterior pituitary-like sex hormone in each cubic centimeter.

The remainder of the Gestrone Chorionic Gonadotropin was alleged to be misbranded in that certain statements in its labeling were false and misleading since they represented and suggested that the article possessed in each cubic centimeter a physiological activity of 500 International Units of anterior pituitary-like sex hormone and that it had been physiologically standardized to that potency, whereas it possessed a physiological activity of not more than 83 International Units of anterior pituitary-like sex hormone in each cubic centimeter.

On January 10, 1945, pleas of guilty having been entered on behalf of the defendants, the court fined the corporate defendant \$250 on each of 3 counts, a total fine of \$750. The individual defendant was sentenced to 3 months in jail on each of the 3 counts, the sentences to run concurrently.

1364. Adulteration of calcium chloride. U. S. v. Pro-Medico Laboratories, Inc., and Samuel Heller. Pleas of guilty. Fines, \$250 against the corporate defendant and \$500 against the individual defendant. (F. D. C. No. 11425. Sample Nos. 36460-F, 36476-F.)

On September 12, 1944, the United States attorney for the Eastern District of New York filed an information against the Pro-Medico Laboratories, Inc., Brooklyn, N. Y., and Samuel Heller, president of the corporation, alleging shipment of a quantity of calcium chloride on or about September 25, 1943, from the State of New York into the State of Colorado.

The article was alleged to be adulterated in that it purported to be and was represented as ampuls of calcium chloride, an aqueous ampul solution the name of which is recognized in the National Formulary, an official compendium, but its quality or purity fell below the official standard since the National Formulary provides that aqueous ampul solutions shall be substantially free from undissolved material, whereas the article was not substantially free from undissolved material; and its difference in quality or purity from the official standard was not plainly stated, or stated at all, on its label.

On January 10, 1945, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of \$250 against the corporate defendant and a fine of \$500 against the individual defendant.

1365. Adulteration and misbranding of potassium chloride. U. S. v. Frederick A. Klenk (Excel Pharmacal Co.). Plea of guilty. Fine, \$250. (F. D. C. No. 9678. Sample No. 9169-F.)

On August 3, 1944, the United States attorney for the Southern District of New York filed an information against Frederick A. Klenk, trading as the Excel Pharmacal Co., New York, N. Y. It was alleged in the information that on or about June 1, 1942, the defendant sold and delivered to the Columbia Medical Laboratories, New York, N. Y., a quantity of an article labeled as "Potassium Chloride"; that at or about the time of the sale and delivery, the defendant furnished to the Columbia Medical Laboratories an invoice containing a guaranty that the article was not adulterated or misbranded within the meaning of the "Federal Food and Drug Act"; that on or about September 22, 1942, the holder of the guaranty introduced and delivered for introduction into interstate com-

merce at New York, N. Y., a quantity of the article for delivery to Jasper, Tex.; and that on or about January 16, 1943, the defendant furnished to the Columbia Medical Laboratories a written instrument to the effect that the guaranties on its invoices, since the Federal Food, Drug, and Cosmetic Act became effective, were to be considered a guaranty under that Act. The information alleged further that the guaranty given by the defendant was false, since the article sold and delivered under the guaranty was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its purity and quality fell below that which it purported and was represented to possess, since it purported to be and was represented to consist of potassium chloride tablets, whereas it consisted of ammonium chloride tablets. It was alleged to be adulterated further in that ammonium chloride tablets had been substituted for potassium chloride tablets.

The article was alleged to be misbranded in that the statement "Potassium Chloride 5 Grains," borne on its label, was false and misleading; and in that it consisted of ammonium chloride and was offered for sale under the name of another drug, potassium chloride.

On August 21, 1944, the defendant having entered a plea of guilty, the court imposed a fine of \$250.

1366. Adulteration and misbranding of solution of epinephrine hydrochloride. U. S. v. Harvey Laboratories, Inc. Plea of nolo contendere. Fine, \$600.
(F. D. C. No. 11433. Sample Nos. 57101-F, 57115-F.)

On July 12, 1944, the United States attorney for the Eastern District of Pennsylvania filed an information against the Harvey Laboratories, Inc., Philadelphia, Pa., alleging shipment on or about September 9 and November 8, 1943, from the State of Pennsylvania into the State of New York of a quantity of ampuls of solution epinephrine hydrochloride. The article was labeled in part: (Boxes containing ampuls) "Epinephrine Hydrochloride, Harvey."

The article was alleged to be adulterated in that it purported to be and was represented as solution of epinephrine hydrochloride, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the standard set forth in that compendium since its potency was not more than 60 percent of that of the official product; and its difference in strength and quality from the official standard was not plainly stated, or stated at all, on the label.

The article was alleged to be misbranded in that the statement, "Solution Epinephrine Hydrochloride 1:1000," on the ampul label, was false and misleading since the article contained not more than 0.6 part of epinephrine hydrochloride in each 1,000 parts.

On September 6, 1944, a plea of nolo contendere having been entered, a fine of \$150 on each of the 4 counts, a total fine of \$600, was imposed.

1367. Adulteration and misbranding of powdered boracic acid. U. S. v. G. C. Gennert (G. Gennert, New York, N. Y.). Plea of guilty. Fine, \$300.
(F. D. C. No. 7203. Sample No. 87105-E.)

On March 30, 1944, the United States attorney for the Southern District of New York filed an information against G. C. Gennert, trading as G. Gennert, New York, N. Y., alleging shipment on or about August 29, 1941, of a quantity of powdered boracic acid from the State of New York into the District of Columbia.

The article was alleged to be adulterated in that a substance, metol, had been mixed and packed with it so as to reduce its quality.

The article was alleged to be misbranded in that the label statement, "Boracic Acid Powdered U. S. P. For Photography," was false and misleading in that the statement represented and suggested that the article conformed with the purpose and object of the United States Pharmacopoeia, namely, that the article, which is recognized in the United States Pharmacopoeia, was fit for medicinal use, whereas the article did not conform with the purpose and object of the United States Pharmacopoeia since it was not fit for medicinal use by reason of the fact that it contained 1.47 percent of metol.

On September 22, 1944, the defendant entered a plea of guilty and was fined \$300.

1368. Adulteration of oil of lemon. U. S. v. Standard Synthetics, Inc. Plea of guilty. Fine, \$100 on each of 5 counts; sentence suspended on 3 remaining counts. (F. D. C. No. 10623. Sample Nos. 11304-F, 11326-F to 11328-F, incl.)

On October 4, 1944, the United States attorney for the Southern District of New York filed an information against the Standard Synthetics, Inc., New

York, N. Y., alleging shipment of a quantity of oil of lemon between the approximate dates of August 19 and December 28, 1942, from the State of New York into the State of California. Portions of the article were labeled in part: "Oil of Lemon Baja Brand," or "Oil of Lemon 'Baja Brand' U. S. P." One lot was invoiced, "Oil of Lemon * * * U. S. P."

A portion of the article was alleged to be adulterated in that it purported to be and was represented as oil of lemon, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality and purity fell below the official standard since it was not the volatile oil obtained by expression, without the aid of heat, from fresh lemon peel, as required by the Pharmacopoeia, but was a lemon oil distillate or mixture of lemon oil distillates; and its difference from the official standard of strength, quality, and purity was not stated on its label.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On October 13, 1944, a plea of guilty having been entered, the defendant was fined \$100 on each of counts 1, 3, 5, 6, and 8 charging adulteration of the product both as a food and a drug. Imposition of sentence was suspended on counts 2, 4, and 7, which counts charged misbranding of the product as a food.

1369. Adulteration and misbranding of Watkins Vitamins A-B-D-G Tablets, and misbranding of Watkins Cod Liver Extract Tablets. U. S. v. The J. R. Watkins Co. Plea of nolo contendere. Fine, \$60. (F. D. C. No. 11432. Sample Nos. 38808-F, 38809-F.)

On January 23, 1945, the United States attorney for the District of Minnesota filed an information against the J. R. Watkins Co., a corporation, Winona, Minn., alleging shipment of quantities of the above-named products during the month of April 1943, from the State of Minnesota into the State of Illinois.

Analysis of the Watkins Cod Liver Extract Tablets disclosed that the article contained 3,465 U. S. P. units of vitamin A and 314 U. S. P. units of vitamin D per tablet. In addition, the article was represented to contain 1 grain of dicalcium phosphate per tablet.

The article was alleged to be misbranded because of misleading statements in an accompanying circular which represented and implied that defective bone and tooth formation, poor health, improper growth, lack of resistance to common cold symptoms, and similar minor infections, dry skin, lack of vigor, diarrhea, digestive disturbances, cessation of growth, physical weakness, formation of kidney and gall stones, catarrh, sinusitis, ear abscesses, restlessness, bowlegs, potbelly, constipation, infantile tetany, convulsions, enlarged joints, softened bones, pigeon breast, curvature of the spine, retarded growth, and marked depletion of calcium and phosphorus in the body commonly and usually result from lack of the vitamins and mineral contained in the article; and that the user might reasonably expect that the consumption of the article would correct such conditions. The conditions referred to in the labeling commonly and usually result from causes other than lack of the vitamins and the mineral contained in the article; and the user might not reasonably expect that consumption of the article would bring about correction, since it would not ordinarily be efficacious for the purposes claimed.

Analysis of the Watkins Vitamins A-B-D-G Tablets disclosed that the article contained not more than 225 U. S. P. units of vitamin A, not more than 100 U. S. P. units of vitamin D, and approximately 0.375 milligram or 125 units of vitamin B₁ (thiamine chloride) per tablet.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since each tablet was represented to contain 2,000 U. S. P. units of vitamin A, 200 U. S. P. units of vitamin D (viosterol), and ½ milligram or 167 units of vitamin B₁ (thiamine chloride), whereas each tablet contained a smaller amount of those vitamins.

The article was alleged to be misbranded in that the statements on its label, "Vitamin A-B-D-G Tablets Each tablet contains: 2,000 U. S. P. Units Vitamin A; 200 U. S. P. Units Vitamin D (Viosterol); ½ Milligram or 167 Units Vitamin B₁ (Thiamine Chloride); * * * Watkins Vitamins ABDG Tablets are biologically and chemically assayed for measured doses," and similar statements in an accompanying circular, were false and misleading. The article was alleged to be misbranded further because of misleading statements in an accompanying leaflet which represented and suggested that low resistance to infections, lack of normal growth, poor appetite, dry skin, lowered resistance to certain types of infection, lack of vigor, diarrhea, digestive disturbances, poor growth, injury to the nerve tissues, neuritis, polyneuritis, loss of appetite, unhealthy skin and mucus mem-

branes, and lack of normal motor, sensory, and central nervous system functions are usually caused by lack of the vitamins contained in the article; and that the user might reasonably expect that the consumption of the article would correct such conditions. The conditions referred to in the labeling commonly and usually result from causes other than lack of the vitamins contained in the article; and the user might not reasonably expect that consumption of the article would bring about their correction, since it would not ordinarily be efficacious for such purposes.

The vitamin tablets were also alleged to be adulterated and misbranded and the cod liver extract tablets were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7919.

On January 23, 1945, a plea of *nolo contendere* having been entered on behalf of the defendant, the court imposed a fine of \$10 on each of 6 counts, a total fine of \$60.

1370. Adulteration of lactate—Ringer's solution. U. S. v. 48 Bottles of Lactate—Ringer's Solution. Default decree of condemnation and destruction. (F. D. C. No. 12512. Sample No. 78667-F.)

On June 10, 1944, the United States attorney for the Northern District of Illinois filed a libel against 48 bottles of lactate—Ringer's solution, at Chicago, Ill., alleging that the article had been shipped by the Continental Hospital Service, Inc., from Cleveland, Ohio, on or about August 6 and 30, 1943.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, namely, for parenteral use, since it was badly contaminated with undissolved material and was not suitable for injecting into the body.

On January 29, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1371. Adulteration of dextrose in distilled water, isotonic solution of three chlorides, and isotonic solution of sodium chloride. U. S. v. 360 Flasks of Isotonic Solution of Sodium Chloride, et al. Consent decrees of condemnation. Product ordered released under bond. (F. D. C. Nos. 12468, 14406. Sample Nos. 76885-F, 76886-F, 81750-F, 81751-F, 82725-F, 82727-F, 82757-F, 82760-F, 83121-F to 83123-F, incl.)

On or about June 2 and November 14, 1944, the United States attorney for the Southern District of New York filed libels against 512 500-cubic centimeter and 1,000-cubic centimeter flasks of isotonic solution of sodium chloride, 18 1,000-cubic centimeter flasks of dextrose in distilled water, and 111 1,000-cubic centimeter flasks of isotonic solution of three chlorides, at New York, N. Y., alleging that the articles had been shipped by Readyflask, Inc., from Lakewood, Ohio, between the approximate dates of February 16 and September 29, 1944.

The articles were alleged to be adulterated in that they purported to be and were represented as isotonic solution of sodium chloride, isotonic solution of three chlorides, and dextrose injection, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and which are required to be free from undissolved material, but their quality and purity fell below the standard set forth therein since they were contaminated with undissolved material.

On July 27, 1944, and January 3, 1945, Readyflask, Inc., claimant for a portion of the products, and William G. Watters and Leon L. Watters, doing business as the Hospital Supply Co. and as the Watters Laboratories, Consolidated, New York, N. Y., claimants for the remainder, having admitted the allegations of the libels, judgments of condemnation were entered and the products were ordered released under bond, conditioned that the contents of the flasks be destroyed, under the supervision of the Food and Drug Administration, and that the flasks be returned to the claimants.

1372. Adulteration of dextrose solution. U. S. v. 1,780 Bottles and 72 Bottles of Dextrose Solution. Default decrees of condemnation and destruction. (F. D. C. Nos. 11843, 11979. Sample Nos. 55825-F, 55839-F, 64941-F.)

On March 4 and 25, 1944, the United States attorney for the Western District of Washington filed libels against 1,852 bottles of dextrose solution at Seattle, Wash., alleging that it had been shipped on or about June 1 and December 14, 1943, by the Cutter Laboratories, Inc., from Berkeley, Calif.; and charging that it was adulterated.

The article was labeled in part: "Dextrose 25% w/v in Fractionally Distilled Water in Saffiflasks," or "Dextrose Solution 50% w/v."

The article was alleged to be adulterated in that it purported to be dextrose injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the article, when examined in the manner specified in the compendium, contained numerous finely divided, undissolved particles, substances not permitted in the official product.

On August 19 and September 16, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1373. Adulteration and misbranding of powdered stramonium leaves. U. S. v. 398 Canisters of Powdered Stramonium Leaves. Default decree of condemnation and destruction. (F. D. C. No. 12339. Sample No. 67250-F.)

On May 11, 1944, the United States attorney for the Western District of Kentucky filed a libel against 398 1-pound canisters of powdered stramonium leaves at Louisville, Ky., alleging that the article had been shipped on or about April 18, 1944, by S. B. Penick & Co., from Jersey City, N. J.

Analysis showed that the article was a mixture of powdered stramonium leaf and a considerable proportion of plant material other than stramonium leaf, including root material such as belladonna root.

The article was alleged to be adulterated in that it purported to be and was represented as stramonium leaves, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard.

The article was alleged to be misbranded in that the statement on the label, "Stramonium Leaves U. S. P., Powdered," was false and misleading.

On July 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1374. Adulteration of double distilled water. U. S. v. 195 Vials of Double Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 12214. Sample No. 67420-F.)

On April 21, 1944, the United States attorney for the Northern District of Ohio filed a libel against 195 vials, each containing 100 cubic centimeters, of the above-named product at Cleveland, Ohio, alleging that it had been shipped on or about January 27 and February 14, 1944, by the Cheplin Biological Laboratories, Inc., Syracuse, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it was represented as a double distilled water, a drug the name of which is recognized in an official compendium, but its quality and purity fell below the official standard since it did not meet the test for oxidizable substances set forth in the National Formulary.

On June 15, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1375. Adulteration of isotonic solution of sodium chloride. U. S. v. 177 Flasks of Isotonic Solution of Sodium Chloride. Default decree of condemnation and destruction. (F. D. C. No. 11827. Sample No. 64940-F.)

On March 1, 1944, the United States attorney for the Western District of Washington filed a libel against 177 flasks, each containing 250 cubic centimeters, of the above-named product at Seattle, Wash., alleging that it had been shipped on or about October 19, 1943, by the Cutter Laboratories, Inc., from Berkeley, Calif.; and charging that it was adulterated.

The article was alleged to be adulterated in that it purported to be sterile isotonic solution of sodium chloride for parenteral use, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not free from undissolved material.

On August 19, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1376. Adulteration and misbranding of adhesive compresses. U. S. v. 900 Packages of Adhesive Compresses. Default decree of condemnation. Product ordered sold. (F. D. C. No. 9737. Sample No. 28935-F.)

On April 2, 1943, the United States attorney for the Northern District of Georgia filed a libel against 900 packages of adhesive compresses at Atlanta, Ga., alleging that the article had been shipped on or about December 28, 1942, by the A. E. Halperin Co., Inc., from Boston, Mass. The article was labeled in part: "1" Adhesive Compresses Unit No. 3."

The article was alleged to be adulterated in that it purported to be adhesive absorbent gauze (adhesive absorbent compress), a drug the name of which is

recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile but was contaminated with living micro-organisms; and its difference in quality and purity from the official standard was not plainly stated on its label.

The article was alleged to be misbranded in that its label failed to bear an accurate statement of the quantity of contents in terms of numerical count.

On May 1, 1945, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be sold, on condition that the packages be stamped "Not sterilized and not to be used on open wounds or as a surgical dressing," and that the product was not to be resold by the purchaser.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

DRUGS FOR HUMAN USE**

1377. Misbranding of Ray-D Tablets. U. S. v. Nion Corporation. Plea of nolo contendere. Fine, \$250. (F. D. C. No. 9672. Sample No. 64965-E.)

On December 1, 1943, the grand jurors for the Southern District of California returned an indictment against the Nion Corporation, Los Angeles, Calif., alleging shipment of a quantity of the above-named article from the State of California into the State of New York between the approximate dates of February 11 and 19, 1942.

Analysis disclosed that the article contained, per tablet, 10 International Units of vitamin B₁, 23 micrograms of riboflavin, and not more than 250 U. S. P. units of vitamin D.

The article was alleged to be misbranded in that certain statements in an accompanying circular were misleading since they represented and implied that the article would be efficacious in the cure, mitigation, treatment, or prevention of impairment of the digestive function, reduction of the motility of the bowel muscle, faulty elimination, malnutrition, and failure to gain weight resulting from lack of vitamin D and the members of the vitamin B complex; that the conditions referred to frequently result from lack of those vitamins; and that the reader might reasonably expect correction and relief from those conditions by use of the product. The article contained inconsequential amounts of vitamin D and the members of the vitamin B complex. The diseases and ailments named usually result from causes other than lack of vitamin D and the members of the vitamin B complex, and a product containing those vitamins would not ordinarily correct and relieve such conditions.

On October 17, 1944, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$250.

1378. Misbranding of Macu Brand Papaya Concentrate. U. S. v. Macu Fruit Products. Motion to quash denied. Plea of guilty. Fine, \$200 and costs. (F. D. C. No. 10602. Sample No. 43991-F.)

On February 9, 1944, the United States attorney for the Northern District of Illinois filed an information against Macu Food Products, a corporation, Chicago, Ill., alleging shipment of a quantity of Papaya Concentrate on or about April 17, 1943, from the State of Illinois into the State of Missouri. The article was labeled in part: "Macu Brand Papaya Concentrate."

The article was alleged to be misbranded in that certain statements in an accompanying circular were false and misleading. It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7921, in which are set forth the results of analysis, and in which are indicated the nature of the false and misleading statements referred to above.

On June 12, 1944, the court entered an order overruling the defendant's motion to quash the information. Thereafter, a plea of guilty was entered on behalf of the defendant, and on November 6, 1944, the court imposed a fine of \$200 and costs.

1379. Misbranding of Colon-ease Herb Tea, Sapomin, Bulko, and Sootherklean. U. S. v. Louis L. Sherman, M. D. (The Layman's Academy of Health). Plea of nolo contendere. Fine, \$40. (F. D. C. No. 11434. Sample No. 42890-F.)

On July 27, 1944, the United States attorney for the Northern District of California filed an information against Louis L. Sherman, M. D., trading as the Lay-

*See also Nos. 1351-1360, 1363, 1365-1367, 1369-1373.

**See also No. 1397.

man's Academy of Health at Oakland, Calif., alleging shipment of a package containing the above-named products on or about October 5, 1943, from the State of California into the State of Washington.

Analysis of the Colon-ease Herb Tea showed that the article consisted essentially of plant material including buchu leaves, cassia bark, juniper berries, celery seed, licorice, and other roots, stems, and leaves. The article was alleged to be misbranded (1) in that the name "Colon-ease" was false and misleading since it suggested and implied that the article would ease the colon, whereas the article would not ease the colon; and (2) in that the statement "Colon-ease," on the jar label, and the statements in the accompanying circular entitled "Directions for Using Package 285," which represented and suggested that the article would ease the colon, keep mucus and scum moving along, aid digestion, relieve gas, aid in the assimilation of food, help stimulate the stomach and liver, relieve nervous tension, soothe the nervous system, help to keep the eliminating organs in a more healthy condition, and make life more worth while were false and misleading since the article would not accomplish the results claimed.

Analysis of the Sapomin showed that the article consisted essentially of small proportions of compounds of calcium, sodium, and aluminum sulfates; traces of compounds of magnesium and iron, chlorides, carbonates, and phosphates; and soap. The article was alleged to be misbranded in that it was not designated solely by a name recognized in an official compendium; and it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient since neither the statement, "Soap Minerals," nor the statement, "Contains: Oxides of Calcium, Magnesium, Silica, Aluminum, Iron, combined with Sulphates and Carbonates. A little powdered soap is added to help dissolve the minerals," borne on the jar label, constituted a statement of the active ingredients of the article by their common names.

Analysis of the Bulko showed that the product consisted essentially of a vegetable gum such as bassorin, a mucilaginous substance such as psyllium, calcium phosphate, dextrose, senna, and other plant material. The article was alleged to be misbranded (1) in that the name "Bulko" was misleading since it represented and implied that the article was solely a bulk-producing preparation, whereas it was not solely a bulk-producing preparation, but contained, in addition, irritant laxative drugs, mandrake and senna; and (2) in that the statement on the carton, "Bulko * * * May be used * * * with detoxication plan," was false and misleading since it represented and suggested that the article alone or in combination with the other articles in the detoxication package would be efficacious in detoxifying the system, whereas the article would not be efficacious for such purpose.

Analysis of the Sootherklean showed that the article consisted essentially of calcium gluconate and phosphate; magnesium sulfate; sodium citrate, bicarbonate, and phosphate; tartaric acid; and cornstarch. The article was alleged to be misbranded (1) in that the name "Soothenklean" was misleading since it represented and implied that the article would soothe and clean the alimentary canal, whereas the article would not be efficacious for such purpose; and (2) in that certain statements on the carton and in the afore-mentioned circular were false and misleading since they represented and suggested that the article would help sweeten and clean the stomach and duodenum, give nature a cleaner place for digestion, and clean the stomach and duodenum of mucus and phlegm, catarrh, or germs that had been swallowed from the teeth, tonsils, and sinus disease. The article would not be efficacious for such purposes.

The articles were alleged to be misbranded further in that the statements in the accompanying circular which represented and suggested that the articles alone or in combination with each other would be efficacious in assuring good health, digestion, assimilation, and the daily elimination of poisons; that they would help the various eliminating organs "Oxydize" and rid the system of poisons; and that they would assist in overcoming kinks and dropped conditions of the colon were false and misleading since the articles, either alone or in combination with each other, would not be efficacious for the purposes recommended.

On August 10, 1944, a plea of nolo contendere having been entered, the defendant was fined \$10 on each of 4 counts, a total fine of \$40.

1380. Misbranding of Nue-Ovo. U. S. v. 143 Packages of Nue-Ovo. Judgment of dismissal in the district court reversed by circuit court of appeals. Petition for writ of certiorari denied by the Supreme Court. Case returned to the district court and tried to the jury. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. No. 1909. Sample No. 16224-E.)

On May 6, 1940, the United States attorney for the Western District of Missouri filed a libel against 143 packages, each containing 3 bottles, of Nue-Ovo at Kansas City, Mo., alleging that the article had been shipped on or about March 15, 1940, from Chicago, Ill., by Nue-Ovo, Inc.; and charging that it was misbranded in that the statements in its labeling, i. e., in the circular entitled "What is Arthritis" accompanying the article, were false and misleading since they represented and suggested that the article was a competent treatment for arthritis, whereas it was not.

Analysis disclosed that the article consisted essentially of extracts of plant drugs, including kola nut, sugars, and water, preserved with sodium benzoate.

On July 11, 1940, the Research Laboratories, Inc., Portland, Oreg., having appeared as intervenor and having filed a motion for removal of the case, an order was entered directing that the case be removed to the Western District of Washington for trial. Thereafter, the intervenor filed exceptions to the libel on the ground (1) that the libel failed to state how and in what manner the Government claimed that the circular accompanied the article; and (2) that the libel failed to state in what particulars the Government claimed the labeling to be false and misleading. Thereafter, the matter came on for hearing before the court, and on December 4, 1940, an order was entered allowing the exceptions and directing that the libel be amended accordingly.

In accordance with this order, an amended libel was filed on or about December 7, 1940, the material allegations of which are set forth hereinafter in the opinion of the circuit court of appeals. Subsequently, the intervenor filed exceptions to the amended libel, and on June 2, 1941, after due consideration of the briefs and arguments of counsel, the court sustained that exception which challenged the sufficiency of the amended libel, and ordered the dismissal of the action. Thereafter, a motion for leave to file a second amended libel was made on behalf of the Government, and on June 16, 1941, an order was entered denying that motion. The case was then taken on appeal to the Circuit Court of Appeals for the Ninth Circuit, and on February 24, 1942, the following opinion was handed down by that court:

MATHEWS, Circuit Judge: "In the District Court of the United States for the Western District of Missouri, 143 packages of a drug called Nue-Ovo were proceeded against by appellant, the United States, on a libel for condemnation under § 304 (a) of the Federal Food, Drug and Cosmetic Act,¹ 21 U. S. C. A. § 334 (a). On application of appellee, Research Laboratories, Incorporated, claimant of the 143 packages of Nue-Ovo, the proceeding was removed to the District Court of the United States for the Western District of Washington. In that court appellant was ordered to, and did, amend its libel. To the amended libel (hereafter called the libel) appellee filed exceptions, one of which was that the libel 'fails to state facts sufficient to constitute a cause of action.' This exception was sustained and the proceeding was dismissed. From the order of dismissal this appeal is prosecuted.

"The libel is crudely and inexpertly drawn. It does not state directly and positively, as a competently drawn libel would have stated, that the 143 packages of Nue-Ovo were misbranded when introduced into or while in interstate commerce. It does, however, state:

¹ Section 304 (a): "Any article of food, drug, device, or cosmetic that is * * * misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, [with inapplicable exceptions]. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court * * * shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

That the said article [Nue-Ovo]² is misbranded in violation of the Federal Food, Drug and Cosmetic Act * * * in that the statements appearing in the labeling thereof, viz., in the circulars entitled "What is Arthritis," accompanying the said article are false and misleading in this, that all and singular of the statement therein and the whole thereof create the impression in the mind of the reader thereof that the said article is a competent treatment for arthritis and excite a feeling of hope and expectation in the mind of a sufferer from arthritis that the use and consumption of said article will be beneficial in treatment of said disease, whereas the said article is not a competent and beneficial treatment for arthritis. * * *

That on or about the 15th day of March, 1940, the said 143 packages, more or less, each containing 3 bottles of an article labeled in part "Nue-Ovo" were shipped * * * in interstate commerce from Chicago, Illinois, by Nue-Ovo, Inc., Chicago, Illinois, * * * to Crown Drug Company, Kansas City, Missouri, and said article now remains unsold in the possession of the Crown Drug Company at Kansas City, Missouri.

That the said circular accompanied said article while in interstate commerce, and thereafter, in the following manner, to-wit:

That a shipment of circulars from Nue-Ovo, Inc., Chicago, Illinois, designated by title as "What is Arthritis" (Exhibit A)³ and containing the same printed words, letters and form, were received in interstate commerce by the Crown Drug Company of Kansas City, Missouri, at its warehouse * * * in said city simultaneously with the said article; that the said circulars and the said shipment of "Nue-Ovo" were placed, then and there, in the same room of the said warehouse for distribution to retail stores of the said Crown Drug Company at Kansas City, Missouri * * *.

"Thus, in substance, the libel states that 143 packages of Nue-Ovo and printed circulars containing false and misleading statements concerning Nue-Ovo were shipped in interstate commerce from Chicago, Illinois, to Kansas City, Missouri, and that all the packages and all the circulars were so shipped by a single shipper (Nue-Ovo, Inc.) to a single consignee (Crown Drug Company) and were by said consignee simultaneously received in interstate commerce.

"These statements must, for present purposes, be taken as true. Taking them as true, we hold that the circulars accompanied the packages and constituted their labeling within the meaning of the Act;⁴ that, since the circulars were false and misleading, the packages were misbranded within the meaning of the Act;⁵ that, since the circulars accompanied the packages in interstate commerce, the packages were misbranded while in interstate commerce within the meaning of the Act; and that, therefore, the packages—and, of course, their contents—are subject to condemnation.

"The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

"Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article.⁶ Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

"The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug and Cosmetic Act is designed, to prevent injury to the public health. *A. O. Andersen & Co. v. United States*, 9 Cir., 284 F. 542, 543; *United States v. 48 Dozen Packages of Gauze*, 2 Cir., 94 F. 2d 641, 642.

"It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled 'What is Arthritis.' The

² The libel does not call Nue-Ovo a drug, but calls it an article. It nevertheless appears from the libel that Nue-Ovo is intended for use in the treatment of disease in man and hence is a drug within the meaning of the Act. See § 201 (g) of the Act, 21 U. S. C. A. § 321 (g). Appellee's brief concedes that Nue-Ovo is a drug.

³ Exhibit A—a copy of the circular entitled "What is Arthritis"—is attached to the libel. The gist of the circular is that Nue-Ovo is a competent and beneficial treatment for arthritis.

⁴ Section 201 (m) of the Act, 21 U. S. C. A. § 321 (m), defines the term "labeling" as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

⁵ Section 502 of the Act, 21 U. S. C. A. § 352, provides:

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular."

⁶ See footnote 4.

power of the District Court to condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order or even by the fact, if it be a fact, that such an order has actually issued.

"There is no merit in appellee's contention that the libel does not sufficiently charge that the circular entitled 'What is Arthritis' is false and misleading. The circular states, in substance and effect, that Nue-Ovo is a competent and beneficial treatment for arthritis. The libel charges that it is not, and that, therefore, the circular is false and misleading. No other charge is necessary.

"Order reversed."

A petition for rehearing was filed by the intervenor and was denied by the court on April 2, 1942; and on April 9, 1942, a mandate issued remanding the case to the district court. A petition for writ of certiorari to the United States Supreme Court by the intervenor was denied on October 12, 1942, following which the intervenor filed an answer to the amended libel, denying that the article was misbranded. The case was tried to a jury, and on June 16, 1943, a verdict for the Government was returned. A proposed decree of condemnation providing for destruction of the product was submitted to the court by the Government. Upon objection by the intervenor, the matter was taken under advisement by the court, and, after consideration of the briefs of the parties, the following memorandum opinion was handed down:

LEAVY, *District Judge*: "This is a libel proceeding instituted by the United States of America under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., against 143 packages, more or less, each containing three bottles of a proprietary medicine called 'NUE-OVO', which were claimed by Research Laboratories, Inc., as being their property.

"The method of labeling in this case was novel and unusual in practice. The sufficiency of the government's libel of information was attacked by the intervenor herein on the ground that it did not state facts sufficient to show a violation of the Federal Food, Drug and Cosmetics Act. After amendment by the government of its original libel of information, the attack was renewed upon the same grounds, and the intervenor's motion to dismiss was sustained by the District Court. Thereupon, the government appealed, and the holding of the District Court was reversed and the cause remanded for trial upon the allegations of the amended libel and the issues made by the further pleadings of the intervenor. *U. S. v. Research Laboratories Inc.*, 126 Fed. 2nd 42.

"Trial upon the issues as made by the pleadings was by jury, resulting in a verdict finding for the government in its contention that the articles were misbranded by reason of the labeling thereof being false and misleading.

"Following the receipt and entry of the verdict herein, plaintiff submitted, upon notice, a form of judgment and decree of forfeiture and condemnation, providing that the United States Marshal shall destroy the said 143 packages of 'Nue-Ovo'.

"At the time fixed by the notice for the presentation of the judgment, the intervenor, Research Laboratories, Inc., appeared and objected thereto, insisting that that part of the decree providing for the destruction of the libeled property should be stricken, and in lieu thereof, a provision made for the sale of the property. The parties requested and were given time to submit written briefs upon this issue.

"It is the contention of the intervenor, Research Laboratories, Inc., that under the facts as disclosed in this case, the court is without discretion to order the destruction of the property, and they contend further that if such discretion, as a matter of law, does exist, it would be an abuse thereof, as well as unjust and inequitable to order its destruction.

"The language of the Act is unambiguous, and clearly places it within the discretion of the court to dispose of the condemned property either by ordering its sale or destruction, so long as the disposition is in accordance with the provisions of the Act. 21 U. S. C. A. 334 (d).

"The conclusions reached here as to the discretionary power of the court in reference to the disposition of condemned property is supported by the following cases: *U. S. vs. Two cans of Oil of Sweet Birch and Three Cans of Oil of Gaultheria*, 268 Fed. 866. *U. S. vs. 1443 Cases, More or less, Canned Salmon*, 7 Fed. Supp. 77.

"In making a disposition of this matter, the court is bound by the facts as they were found by the jury, upon the issues submitted to it. The issue made by the pleadings and directly submitted by the court's charge to the jury for its consideration was whether there was a misbranding by reason of the labeling being false or misleading, and this, in turn, included the issue as to whether the

medicine involved herein had any value whatever in the beneficial treatment of arthritis in any of its forms.

"It was conceded by all parties that 'Nue-Ovo' was not injurious or harmful. The verdict of the jury is the equivalent of a finding:

"1. That the labeling of 'Nue-Ovo' was false and misleading.

"2. That the substance 'Nue-Ovo' was useless and valueless as a remedy in the treatment of arthritis.

"In passing upon the matter now before the court, therefore, it is not a question of what the court may think concerning the facts, but the facts that were found by the jury's verdict must be accepted, and since the jury has found that there was a misbranding by reason of false and misleading labeling, and also found that the article in question has no therapeutic value in the treatment of arthritis, it would be an abuse of discretion on the part of the court to direct its sale, and thus permit it to again become an article of commerce.

"The only purpose of placing 'Nue-Ovo' on the market was as a beneficial treatment for arthritis. The findings of the jury to the effect that it was not such treatment make it inconsistent to direct its sale and movement back into the channels of commerce and trade.

"I, therefore, overrule the objections interposed by the intervenor, Research Laboratories, Inc., and upon the re-submission of the judgment and decree of forfeiture and condemnation, the same will be signed."

On August 3, 1943, judgment of condemnation was entered ordering that the article be destroyed; and on October 1, 1943, the motion for a new trial, which had been filed by the intervenor was denied.

1381. Misbranding of Azmarin Tablets. U. S. v. 140 Packages of Azmarin Tablets. Default decree of condemnation and destruction. (F. D. C. No. 12322. Sample No. 60334-F.)

On May 10, 1944, the United States attorney for the Northern District of California filed a libel against 140 packages of Azmarin Tablets at San Francisco, Calif., alleging that the article had been shipped on or about April 5, 1944, by the Azmarin Co., from Miami, Fla.

Examination showed that the article consisted essentially of aspirin, 4.4 grains per tablet, with small proportions of sulfur, potassium bitartrate, and plant material.

The article was alleged to be misbranded because of false and misleading statements on the box label and in the accompanying leaflets entitled "Azmarin Tablets and Method of Treatment in Colds & Coughs," and "What Every Sufferer From Colds, Catarrh, Hay Fever, Sinus, Bronchitis and Asthma Should Know," regarding its efficacy in the prevention or treatment of colds, coughs, excess mucus conditions, catarrh, hay fever, sinus trouble, bronchitis, asthma, influenza, bad conditions of the blood, spasm, acid conditions, irritated or inflamed mucous membrane, nervousness, difficult breathing, and choking and smothering spells. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, since aspirin had been designated on the label as acid acetylsalicylic.

On September 14, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1382. Misbranding of DPS Formulae 80, 81, and 200. U. S. v. 11 Bottles of DPS Formula 80, 7 Bottles of DPS Formula 81, 14 Bottles of DPS Formula 200, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 12354. Sample Nos. 54123-F, 54177-F, 54178-F.)

On or about May 19, 1944, the United States attorney for the District of Arizona filed a libel against 11 4-ounce bottles of Formula 80, 7 100-tablet bottles of Formula 81, 14 90-tablet bottles of Formula 200, and a quantity of printed matter at Phoenix, Ariz., alleging that the articles and the printed matter had been shipped on or about February 29 and March 15, 1944, by the Dartell Laboratories, Los Angeles, Calif. The printed matter consisted of 12 index cards entitled "DPS Series 80," 12 folders entitled "DPS Series 80 * * * Improved Method For The Use of Chlorophyll In The Treatment of Disease," 25 circulars entitled "Amino Acid Formula Victory Over Achlorhydria And Sequelae," and a booklet entitled "DPS Dartell Formulae."

Examination disclosed that the Formula 80 consisted of an aqueous solution of sodium chloride and a compound of chlorophyll; that the Formula 81 consisted essentially of a soluble chlorophyll derivative incorporated in tablet

form with alfalfa; and that the Formula 200 consisted of tablets containing approximately 5 grains each of glutamic acid hydrochloride and a proteolytic enzyme coated with a mixture containing calcium carbonate.

The articles were alleged to be misbranded because of false and misleading statements in the labeling regarding their efficacy in the treatment of the following conditions: (Formula 80) sinusitis, nasal disorders, tonsillitis, otitis, pyorrhea, gingivitis, angina, stomatitis, vulvar eczema, vulvitis, *Trichomonas* infestation, cervicitis, cervical ulcer, erosions, pruritus ani, fissure in ano, ulcer, skin diseases, athlete's foot, impetigo, boils, carbuncles, acne vulgaris, herpes zoster, herpes labialis, anemia, high blood pressure, rhinitis, rhinopharyngitis, hypertension, auto-intoxication, severe, suppurating wounds, kidney abscesses, pus in the lung cavity, ruptured appendix, peritonitis, denuded areas where skin graft is indicated, and leukorrhea; (Formula 81) anemia, high blood pressure, disorders of the circulatory system, vitamin and mineral deficiencies, hypertension, cardiovascular conditions, toxic conditions, impaired cellular respiration, and infections; (Formula 200) anemia, malnutrition, gastric carcinoma, chronic gastritis, pellagra, scurvy, sprue, gallbladder disease, myxedema, nephritis, diabetes mellitus, Addison's disease, tuberculosis, arteriosclerosis, hyposthenic neurosis, hyperthyroidism, arthritis, and other conditions of gastric origin, colitis, diarrhea, various endocrine dysfunctions, degenerative lesions of heart, liver, kidneys, and blood vessels, high blood pressure, toxic reactions and allergies, and vitamin and mineral deficiencies.

On July 12, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1383. Misbranding of Dr. Stover's Golden Oil. U. S. v. 67 Bottles of Dr. Stover's Golden Oil. Default decree of condemnation and destruction. (F. D. C. No. 12503. Sample No. 28868-F.)

On or about June 19, 1944, the United States attorney for the Southern District of Florida filed a libel against 67 bottles, each containing 6 fluid ounces, of the above-named product at Orlando, Fla., alleging that the article had been shipped on or about April 3 and May 6, 1944, by the Planet Products Co., from Detroit, Mich.

Analysis of a sample disclosed that the article consisted essentially of mineral oil, small amounts of camphor, oil of mustard, oil of eucalyptus, and oil of thyme.

The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular regarding its efficacy in the treatment of arthritis, rheumatism, neuritis, chest colds, sore throat, croup, crippled bodies, legs, and arms, twisted hands and fingers, shortened muscles, swollen joints, and tense and tired nerves.

On August 17, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1384. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. 14 Bottles and 3 Bottles of Colusa Natural Oil and 58 Circulars (and 54 other seizure actions against Colusa Natural Oil and Colusa Natural Oil Capsules and circulars). Default decrees of condemnation. Portion of products ordered delivered to the Food and Drug Administration; remainder ordered destroyed. (F. D. C. Nos. 12717, 13127, 13308, 13334, 13369, 14724, 14725, 14727 to 14729, incl., 14732 to 14735, incl., 14737 to 14739, incl., 14741 to 14744, incl., 14754, 14765 to 14767, incl., 14777, 14788, 14796, 14805, 14806, 14810, 14814, 14817, 14818, 14823, 14845, 14912, 14923 to 14925, incl., 14941, 14942, 14952, 14959, 15003, 15017, 15162, 15175, 15229, 15424, 15477, 15664, 15815, 15833, 15925. Sample Nos. 3842-F, 3843-F, 26669-F, 26701-F, 61810-F, 61811-F, 61971-F, 63350-F, 63351-F, 63790-F, 64096-F, 64097-F, 64217-F, 64218-F, 64223-F, incl., to 64232-F, incl., 68193-F, 68194-F, 68573-F, 68574-F, 71048-F, 71565-F, 74564-F, 74565-F, 74772-F, 74773-F, 75785-F, to 75787-F, incl., 78164-F, 78165-F, 79777-F, 81279-F, 81280-F, 81712-F, 81713-F, 82890-F, 82891-F, 82897-F, 82898-F, 83038-F, 83039-F, 83805-F, to 83810-F, incl., 83857-F, 83858-F, 83883-F, 85277-F, 85280-F, 87582-F, 87583-F, 87755-F, 87756-F, 87824-F, to 87826-F, incl., 87830-F, 87831-F, 87835-F, 87836-F, 87926-F, 87927-F, 88523-F, 88524-F, 90077-F, 90078-F, 90813-F, 90814-F, 92039-F, 92040-F, 92390-F, 92391-F, 96884-F, 901-H, 5887-H, 11617-H to 11620-H, incl., 13507-H, 13509-H, 13510-H, 13520-H, 13706-H, 13707-H, 22336-H, 22337-H, 22449-H, 22812-H, 22813-H, 24133-H.)

Between June 24, 1944, and April 18, 1945, there were filed in the appropriate Federal District Courts 55 libels against a total of 1,756 2-ounce bottles and 382 4-ounce bottles of Colusa Natural Oil, and 706 100-capsule boxes and 264 200-capsule boxes of Colusa Natural Oil Capsules, including quantities of circulars headed "Colusa Remedy Co. Field Headquarters Williams, California."

It was alleged in the libels that the drugs and the circulars were located at the following places: Oregon City, Portland, Salem, Albany, and Medford, Oreg.;

Woodbury, Union City, Hoboken, and Newark, N. J.; Wichita Falls and Denison, Tex.; Asheville, Salisbury, and North Wilkesboro, N. C.; St. Paul, Minn.; Fargo, N. Dak.; Meadville, Lewistown, Erie, and Reading, Pa.; Norwich and Waterbury, Conn.; Baton Rouge, La.; Elkins, W. Va.; Enid, Okla.; Yakima and Spokane, Wash.; Caldwell, Idaho; Butte, Mont.; Fort Dodge, Dubuque, and Sioux City, Iowa; Columbus, Lima, Cambridge, Portsmouth, and Lorain, Ohio; Anderson, Columbia, and Greenwood, S. C.; Vicksburg, Miss.; Athens and Columbus, Ga.; Coffeyville, Kans.; La Crosse and Wisconsin Rapids, Wis.; Cape Girardeau, Mo.; Lockport and Troy, N. Y.; Miami, Fla.; West Frankfort and Du Quoin, Ill.; Nashua, N. H.; and Pine Bluff, Ark.

It was also alleged in the libels that the drugs had been shipped between the approximate dates of March 8, 1944, and February 15, 1945, by the Colusa Remedy Co., from Los Angeles, Calif.; and that the circulars, which were shipped, in some instances, with the drugs and, in other instances, before or after the drugs had been shipped, accompanied the drugs when they were introduced into and while they were in interstate commerce.

The bottle labels and boxes bore the statement: "Natural Unrefined Petroleum Oil." Examination of samples of the products disclosed the composition to be as stated.

The drugs were alleged to be misbranded in that certain statements in the circulars and the pictures of a man's back, two hands, and a leg before and after treatment were false and misleading, since the statements and pictures represented and suggested that the drugs would be efficacious in the treatment of psoriasis, eczema, leg ulcers, itch, and athlete's foot. When used alone or in combination with each other, they would not be efficacious for such conditions.

Between August 11, 1944, and May 22, 1945, no claimant having appeared, judgments of condemnation were entered and portions of the products and circulars were ordered delivered to the Food and Drug Administration, and the remainder were ordered destroyed.

1385. Misbranding of Marvel Herb Tea. U. S. v. 138 Packages and 447 Packages of Marvel Herb Tea. Default decree of condemnation and destruction.
(F. D. C. No. 12330. Sample No. 76998-F.)

On May 6, 1944, the United States attorney for the District of New Jersey filed a libel against 138 3-ounce packages and 447 7-ounce packages of the above-named product at Jersey City, N. J., alleging that the article had been shipped on or about December 7, 1943, from Pittsburgh, Pa., by the Marvel Products Co., Inc.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that the statement on the packages, "Minimum weight of contents 3 ounces [or "7 ounces"] when packed," was false and misleading as applied to the article, which was short-weight; and (2) in that its label failed to bear an accurate statement of the quantity of contents.

On July 10, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1386. Misbranding of Munyon's Paw Paw Tonic. U. S. v. 60 Packages of Munyon's Paw Paw Tonic. Default decree of condemnation and destruction.
(F. D. C. No. 12137. Sample No. 52843-F.)

On April 4, 1944, the United States attorney for the Eastern District of Virginia filed a libel against 60 packages of the above-named product at Norfolk, Va., alleging that the article had been shipped on or about July 30, 1943, by Phoenix Preparations, from Scranton, Pa.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, extracts of plant drugs, including strychnine and an emodin-bearing drug, together with a trace of an iron compound.

The article was alleged to be misbranded in that certain statements in the labeling were false and misleading since the article contained no ingredients which would be effective in producing the results claimed. These statements represented and suggested that the article would be efficacious in the treatment of dyspepsia, indigestion, dizziness, poor circulation, sleeplessness, nervousness, constipation, weakness, general debility, all stomach troubles, loss of vitality, liver and blood ailments, catarrh, kidney and rheumatic complaints, syphilis, and weak heart. The labeling further represented and suggested that the article would dissolve albumen; that it would tone the stomach, liver, and nerves; that it would build nerves and muscles; that it would build up the system when suffering from catarrh; that it would aid body strength and mental force; that it would furnish good, rich blood; that it would give life and snap to the overworked and rundown, and make old folks feel strong; that it would drive out

poisons and impurities of the blood; that it would bring back strength and vitality; and that it would be an excellent vermifuge.

On May 30, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1387. Misbranding of Rolle Garlic and Parsley with Honey. U. S. v. 144 Bottles of Rolle Garlic and Parsley with Honey, and a quantity of circulars. Default decree of destruction. (F. D. C. No. 12251. Sample No. 40288-F.)

On July 19, 1944, the United States attorney for the District of Minnesota filed a libel against 144 4-ounce bottles of the above-named article and a quantity of circulars at Faribault, Minn., alleging that the article had been shipped on or about March 2, 1943, and April 6, 1944, by Rolle Vegetable Juices, Inc., from Chicago, Ill.

Examination showed that the product was essentially a sweetened water extract of garlic and parsley.

The article was alleged to be misbranded because of false and misleading statements in accompanying circulars entitled "Rolle Garlic and Parsley with Honey" regarding its efficacy as an antiseptic and its efficacy in the treatment of a wide variety of symptoms, conditions, and diseases, including diarrhea, high blood pressure, heart and artery diseases, tuberculosis, numbness, dizziness, pneumonia, shortness of breath, and digestive disorders.

On October 6, 1944, no claimant having appeared, judgment was entered ordering the product destroyed.

1388. Misbranding of Wiel Garlic Tablets. U. S. v. 57 Bottles and 60 Tins of Wiel Garlic Tablets. Default decree of condemnation and destruction. (F. D. C. No. 12402. Sample No. 60735-F.)

On May 17, 1944, the United States attorney for the Northern District of California filed a libel against 57 bottles labeled as containing 120 garlic tablets and 60 tins labeled as containing 24 garlic tablets, at Berkeley, Calif., alleging that the article had been shipped on or about March 27, 1944, by the Wiel Laboratories, from Medford, N. Y.

Analysis of the article showed that it was a garlic tablet coated with mint-flavor sugar.

The article was alleged to be misbranded because of false and misleading statements on its label regarding its efficacy in building better health, stimulating digestion, and reducing high blood pressure when taken continuously at prescribed intervals. A portion of the article (120-tablet bottles) was alleged to be further misbranded in that it failed to bear an accurate statement of the quantity of the contents, since the bottles contained less than 120 tablets.

On October 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1389. Misbranding of Benefax Vitamin B Complex, Benefax Vitamins A & D, and Benefax Multi Vitamins. U. S. v. 44 Boxes and 22 Bottles of Benefax Vitamin B Complex, 332 Boxes and 166 Bottles of Benefax Multi Vitamins, and 310 Boxes and 166 Bottles of Benefax Vitamins A & D. Decrees of condemnation. Products ordered released under bond. (F. D. C. No. 12121. Sample No. 33885-F.)

On April 3, 1944, the United States attorney for the Western District of New York filed libels against the above-mentioned products at Rochester, N. Y., alleging that the articles had been shipped on or about September 25, 1943, by the Anacin Co., from Jersey City, N. J.

The articles were alleged to be misbranded in that certain statements in the labeling were misleading. The articles were also alleged to be misbranded under the provisions of law applicable to foods, as reported in notices of judgment on foods, No. 7902, in which are set forth in full the results of analyses and the misleading statements referred to above.

On April 16, 1945, the Whitehall Pharmacal Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond, conditioned that the display cards be destroyed.

1390. Misbranding of Bates vitamin preparations. U. S. v. 104 Bottles of Bates Calcium Pantothenate Dextrorotatory, 116 Bottles of Bates Multiple Vitamin Tablets, 32 Bottles of Bates Vitamin A & D, 34 Bottles of Bates Natural B Complex, 20 Bottles of Bates (Nicotinic Acid) Niacin, 20 Bottles of Bates (Thiamine) Vitamin B₁, 20 Bottles of Bates Riboflavin Vitamin B₂ (G), and 20 Bottles of Bates (Ascorbic Acid) Vitamin C. Default decree of condemnation and destruction. (F. D. C. No. 12426. Sample Nos. 60550-F to 60557-F, incl.)

On May 24, 1944, the United States attorney for the Northern District of California filed a libel against the above-mentioned products at San Francisco,

Calif., alleging that the articles had been shipped by the Bates Laboratories, Inc., between the approximate dates of March 31, 1943, and January 17, 1944, from Chicago, Ill.

The articles were alleged to be misbranded in that certain statements in the labeling were false and misleading since the articles, either singly or in combination, would not fulfill the promises of benefit expressed or implied in the labeling.

They were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7910, in which the false and misleading statements referred to above are set forth in full.

On October 2, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1391. Misbranding of hair preparations. U. S. v. 13 Packages of Junior Beginners Assortment Parker Herbex Preparations. Default decree of condemnation and destruction. (F. D. C. No. 12263. Sample Nos. 56984-F to 56999-F, incl.)

On May 6, 1944, the United States attorney for the District of New Jersey filed a libel against 13 packages of an article labeled, in part, "Junior Beginners Assortment Parker Herbex Preparations," at Newark, N. J., alleging that the article had been shipped on or about October 2, 1942, by the New York Hair Co., from New York, N. Y.

Each package of the article contained one each of a number of hair preparations labeled "Areata Salve," "Special Pink Ointment," "Special White Ointment," "Standard Yellow Ointment," "Conditioner No. 3," "No. 2," "Special Tincture Mullein," "Special Tincture Jaborandi," "G. O. S. Shampoo," "No. 1," "Hair Softener," "Triple X," "Areata Special," "Special Tincture Capsicum," "Specially Prepared Bluing," and "Exite," and printed matter including a circular entitled "Hair Hygiene For Hairdressers and How To Use Herbex," a 152-page booklet entitled "Official Operator's Copy of the 1942 Edition of the Parker Herbex Manual," and a chart entitled "Handy Operator's Guide for Parker Herbex Hair and Scalp Treatments." The packages were accompanied by a number of charts entitled "Parker Herbex Professional's Chart," one of which was included with each sale of the packages.

Examination of samples showed that the Areata Salve consisted essentially of small proportions of chrysarobin, sulfur, and salicylic acid in a perfumed petrolatum base; that the Special Pink Ointment consisted essentially of thymol, salicylic acid, sulfur, and glycerin in a petrolatum base; that the Special White Ointment consisted essentially of a perfumed petrolatum ointment with little, if any, cantharides; that the Standard Yellow Ointment consisted essentially of a perfumed mixture of sulfur and salicylic acid in a petrolatum base with little, if any, cantharides; that the Conditioner No. 3 consisted essentially of chloral hydrate, glycerin, water, and little, if any, cantharides; that the No. 2 consisted essentially of alcohol, water, and extracts of plant drugs including little, if any, capsicum and cantharides; that the Special Tincture Mullein consisted essentially of alcohol, water, and extract of plant materials such as mullein; that the Special Tincture Jaborandi consisted essentially of alcohol, water, and extract of plant material; that the G. O. S. Shampoo consisted essentially of water, soap, and glycerin; that the No. 1 consisted essentially of alcohol, water, and extracts of plant drugs such as soap bark; that the Hair Softener consisted essentially of water, a sulfonated oil, glycerin, and sodium carbonate; that the Triple X consisted essentially of perfume, alcohol, water, chloral hydrate, and extracts of plant drugs including little, if any, capsicum or cantharides; that the Areata Special consisted essentially of water, chloral hydrate, and extracts of plant drugs including little, if any, capsicum or cantharides; that the Special Tincture Capsicum consisted essentially of alcohol, capsicum oleoresin, and water; and that the Exite consisted essentially of alcohol, water, mustard oil, and extracts of plant materials.

Misbranding was alleged in the libel in that certain statements on the labels and in the printed matter were false and misleading since they represented and suggested that the products, either alone or in combination, would be effective in the treatment of dandruff, itchy scalps, scalp irritations accompanied by eruptions or mattery secretions, eruptions or pimples of the scalp, dry, broken or brittle hair, falling hair, thin, poor hair, alopecia areata, receding hair line, all types of curable baldness, scalp eczema, seborrhea, psoriasis, pityriasis, split ears and red spots around the hair line, sick hair of all kinds, and falling hair due to operations or childbirth; and that the products would stimulate the flow of pigment through the hair shaft, prevent premature grayness, soften harsh, dry,

brittle hair, stimulate the muscles of the appendages of the hair, act as a healing agent in certain types of scalp disorders, grow hair, tone the scalp, prevent dandruff, keep the hair and scalp healthy, and stimulate the flow of blood to the surface of the scalp, whereas the products, either alone or in combination, would not be efficacious for such purposes.

The Special Pink Ointment was alleged to be misbranded further in that its label failed to bear the common or usual name of each active ingredient.

On August 14, 1944, no claimant having appeared, judgment of condemnation was entered and the products and printed matter were ordered destroyed.

1392. Misbranding of Kotalko. U. S. v. 126½ Dozen Packages and 96 Dozen Packages of Kotalko. Consent decree of condemnation. Product ordered released under bond. F. D. C. Nos. 12639, 12670. Sample Nos. 76499-F, 76999-F.)

On May 19 and June 15, 1944, the United States attorney for the District of New Jersey filed libels against 222½ dozen packages of Kotalko at Jersey City, N. J., alleging that the article had been shipped between the approximate dates of January 28 and May 12, 1944, by the Kotalko Sales Co., from New York, N. Y.

Examination showed that the article consisted essentially of an ointment containing, among other ingredients, sulfur and a camphoraceous oil. The box containing the ointment occupied approximately 40 percent of the volume of the carton. The carton also contained circulars entitled "Kotalko Dictory," and "Important Truth Revealed." The article was alleged to be misbranded in essentially the same way that the product described in notices of judgment on drugs and devices, No. 1337, was misbranded.

On November 6, 1944, Rose R. Scott, trading as the Kotalko Sales Co., claimant, having admitted the allegations of the libels, and the cases having been consolidated, judgment of condemnation was entered and the product was ordered released under bond, conditioned that the circulars be destroyed and replaced with new circulars correctly characterizing the product, under the supervision of the Food and Drug Administration.

1393. Misbranding of menthol inhalers. U. S. v. 126 Cartons of Menthol Inhalers. Default decree of condemnation and destruction. (F. D. C. No. 11911. Sample No. 60702-F.)

On February 29, 1944, the United States attorney for the Northern District of California filed a libel against 126 cartons, each containing 12 menthol inhalers, at San Francisco, Calif., alleging that the article had been shipped on or about February 9 and April 9, 1943, by the Eagle Druggists Supply Co., from New York, N. Y.; and charging that it was misbranded.

Examination disclosed that the article contained less than the 7 grains of menthol declared on the label, the average shortage being 17.7 percent.

The article was alleged to be misbranded (1) in that the label statement, "Menthol 7 Grains," was false and misleading since the article did not contain 7 grains of menthol; and (2) in that its label failed to bear an accurate statement of the quantity of the contents, since the statement made was incorrect.

On October 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1394. Misbranding of Miracle Electric Massager. U. S. v. 38 Miracle Electric Massagers. Default decree of condemnation and destruction. (F. D. C. No. 12438. Sample No. 15049-F.)

On May 25, 1944, the United States attorney for the Southern District of California filed a libel against 38 Miracle Electric Massagers at Los Angeles, Calif., alleging that the article had been shipped on or about February 20, 1944, by Miracle Products, Inc., from Chicago, Ill.; and charging that it was misbranded.

The article consisted of a vibrator operated by an electric motor.

The article was alleged to be misbranded because of false and misleading statements on the carton and in an accompanying circular entitled "It's a Miracle! Electric Massager" which represented and suggested that the article would relieve headaches, pain, stiffness, colds, sore muscles, backaches, nervousness, and sleeplessness; that it would be efficacious in the treatment of rheumatism, in relaxing tired muscles, in conditioning the skin and scalp, and in improving complexions and the natural functions of the body; and that it would be beneficial in the preservation and growth of hair, in reducing fat, and in maintaining the vitality and tone of the muscles.

On June 16, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that the article and all advertising matter be destroyed.

DRUGS FOR VETERINARY USE

1395. Misbranding of Lippincott's Poultry Remedy. U. S. v. 165 Bottles of Lippincott's Poultry Remedy. Default decree of condemnation and destruction. (F. D. C. No. 12191. Sample Nos. 55173-F to 55175-F, incl.)

On April 15, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 27 12-ounce bottles, 69 6-ounce bottles, and 69 3-ounce bottles of the above-named product at Detroit, Mich., alleging that the article had been shipped on or about December 21, 1943, by John W. Lippincott, Newark, Ohio; and charging that it was misbranded.

Analysis of the article showed that it was a brownish-black liquid of two layers, consisting chiefly of crude kerosene, water, catechu, sulfur, and a manganese compound.

The article was alleged to be misbranded in that the statements in the labeling which represented and suggested that it would be efficacious as an expectorant and as an aid in the relief of internal parasites, and that it would be efficacious for the relief of common colds in fowl and for the relief of "dopie" chicks, were false and misleading. The product, when used as directed would have no value in the prevention or treatment of any known disease condition of poultry; and it would be of no value as an expectorant, as an aid or relief from any known internal parasites, or for chicks in the depressed condition referred to as "dopie."

On May 24, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1396. Misbranding of Revitalizer and Wormex. U. S. v. 1,178 Containers of Revitalizer and 21 Bags of Wormex. Default decree of condemnation and destruction. (F. D. C. No. 12334. Sample Nos. 77508-F to 77510-F, incl.)

On May 15, 1944, the United States attorney for the District of New Jersey filed a libel against 1,149 22-ounce cartons and 29 10-pound bags of Revitalizer and 21 10-pound bags of Wormex at Newark, N. J., alleging that the articles had been shipped on or about January 12 and February 21, 1944, by the Dailey Mills, Inc., from Binghamton, N. Y.

The Revitalizer, according to the statement of ingredients on its label, was a mixture of feeds with calcium carbonate, potassium iodine, manganese sulfate, and salt added, fortified with a vitamin A and D feeding oil. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and implied that the article would be effective as a vitamin stimulant of poultry; that it would condition chicks, promote growth, retard disease, tone up the system, and help keep birds healthy and productive; and that it would assure prime condition of birds at all times, build resistance to disease, supply an overabundance of a balanced group of the proper vitamins, increase egg production, lower mortality, cleanse the entire digestive tract, overcome overheating and chilling due to shipping, sharpen appetites, eliminate excessive mucus in the intestines, restore the body vigor, and supply the system with a surplus of vitamins and minerals. The article would not be effective for such purposes.

The Wormex, according to the statement of ingredients on its label, was essentially a feed with which the following drugs had been incorporated: Nux vomica, Areca nut, copperas, fenugreek, oil of Chenopodium, quassia, and gentian. The article was alleged to be misbranded because of false and misleading statements on the bag label and in an accompanying circular entitled "Ready-Mixed Wormex for all Poultry" which represented and suggested that the article would be effective against all species of worms, as the name "Wormex" implied; and that it would be effective against all species of round-worms and for cecal worms. It would not be effective for such purposes.

On December 4, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1397. Misbranding of Mar-To-Ma Chick Rem, Compound Powder, Myero Rem, and Cough & Cold Mixture. U. S. v. 10 Packages of Mar-To-Ma Chick Rem, 12 Packages and 23 Cans of Mar-To-Ma Compound Powder, 9 Packages of Mar-To-Ma Myero Rem, and 16 Bottles of Mar-To-Ma Cough & Cold Mixture. Default decrees of condemnation and destruction. (F. D. C. No. 12332. Sample Nos. 49933-F to 49936-F, incl.)

On May 10, 1944, the United States attorney for the Western District of New York filed libels against the above-named products at Holland, N. Y., alleging that the articles had been shipped between the approximate dates of October 30, 1943, and January 26, 1944, by T. H. Speigelmire & Son, from Selinsgrove, Pa.; and charging that they were misbranded.

The label for the Chick Rem bore the following statement of ingredients: "Epsom Salt, Potassium Sulphate, Acetic Acid, Tomato Pulp, Extract Asafetida, Brewer's Yeast, Sulphur, Lactic Acid, Phenothiazine, Propionic Acid, Pepsin." Analysis of a sample of the article showed that it contained, among other ingredients, Epsom salt, potassium sulfate, asafetida, and other organic material. It was alleged to be misbranded in that the following statements in its labeling were false and misleading: "Recommended as an aid in the treatment of Coccidiosis and Blackhead in its first stages, and other bowel and liver disorders, diarrhoea, etc. For Baby Chicks, Turkey Poults, Old Hens, Turkeys, Pigs, Calves, etc. * * * As a Preventive * * * Once Coccidiosis or Blackhead has developed, use 18 tablespoonfuls to 100 lbs. of mash for 4 days then as before * * * Once Coccidiosis or Blackhead has developed use 6 tablespoonfuls to 5 gallons of water * * * Also prevents the dauby rear end. * * * Poultrymen find this Chick-Rem very helpful in laying hens and turkeys, in keeping the bowels in good order by using the above dosage. Farmers are finding it very helpful to treat farm stock and pigs by giving heavier doses till bowels are normal. (Helpful in Diarrhea, Scours, etc.); and "Chick Rem is put in this wet mash for 1 day, every 5 to 7 days to prevent Coccidiosis, or if they have it, feed the wet mash for 4 days straight, wonderful results will be obtained in keeping birds well." A product of the composition stated, when used as directed, alone, or in conjunction with Mar-To-Ma Compound Powder, would not be effective in the prevention or treatment of any disease conditions of animals, including poultry.

The label for the Compound Powder bore the following active ingredient statements: "Sodium Sulphate, Flowers Sulphur, Magnesium Sulphate, Powdered Charcoal, Powdered Licorice Root, Magnesium Carbonate, Iron Carbonate, Phenothiazine, Irradiated Yeast, Manganese Sulphate." Analysis of a sample of the article showed that it contained, among other ingredients, sulfates and carbonates of sodium, magnesium, iron, manganese, and organic material. It was alleged to be misbranded in that the following statements on its label were false and misleading: "as an aid in the treatment of disordered bowels. Will assist in eliminating some of the worms from which poultry and livestock suffer. * * * Give till desired results are obtained. * * * To assist in worming for two weeks only, use 3 tablespoonfuls to 5 gallons of water, then return to 2." The product when used as directed would not be effective in the prevention or treatment of any disease conditions of animals, including poultry.

The label for the Mycro Rem bore the following ingredient statement: "Epsom Salt, Acetic Acid, Extract Asafetida, Sulphur, Lactic Acid, Propionic Acid, Potassium Sulphate, Tomato Pulp, Brewer's Yeast, Phenothiazine, Pepsin, Copper Sulphate." Analysis of a sample of the article showed that it contained, among other ingredients, copper sulfate, potassium sulfate, Epsom salt, asafetida, and other organic material. It was alleged to be misbranded in that the following statements on its label were false and misleading: "Mycro Rem * * * Recommended as an aid in the treatment of Mycosis (Gizzard Erosion) and other bowel disorders for Chicks, Turkey Poults, Ducks, Geese, Old Hens, Turkeys, Pigs, Calves, etc. Recommended to be fed with our Compound Powder and Chick Rem. * * * After birds and animals have recovered, repeat once a week for one day as a preventative of recurrence of this illness. * * * Our Mar-To-Ma Compound Powder should be fed continually as it helps restore healthy organs which is necessary for health." The product, when used as directed, alone, or in conjunction with the Compound Powder and Chick Rem, would not be effective in the prevention or treatment of any disease conditions of animals, including poultry.

Analysis of a sample of the Cough & Cold Mixture showed that the article was essentially a water solution of sugar and guaiacol. It was alleged to be misbranded in that the following statements on its label were false and misleading: "Cough and Cold Mixture * * * Coughs, Colds, Bronchial Affections. For the Respiratory Tract. * * * Cold is broken * * * cold is broken * * * Cold Remedy * * * is also recommended for Colds in Chickens, Turkeys, Baby Chicks, Turkey Poults, Mink, Dogs, Cats, Foxes, Pigs, Horses, Cows, etc. * * * until relieved." The product when used as directed would not be effective in the treatment of colds, bronchial affections, or other disease conditions of the respiratory tract of man or other animals.

On June 19, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1398. Misbranding of Barker's Poultry Powder, Spray Inhalant for Poultry, Hog Round Worm Powder, and Poultry Round Worm Powder. U. S. v. 4 Bags of Barker's Poultry Powder (and 1 other seizure action against Barker's Spray Inhalant for Poultry, Hog Round Worm Powder, and Poultry Round Worm Powder). Default decrees of condemnation. Portion of products ordered delivered to a charitable institution; remainder ordered destroyed. (F. D. C. Nos. 11321, 11590. Sample Nos. 50727-F, 50730-F, 50731-F, 50733-F.)

On or about December 15, 1943, and January 14, 1944, the United States attorney for the District of New Jersey filed libels against 4 100-pound bags of Barker's Poultry Powder at Mount Holly, N. J., and against 10 1-pint bottles of Barker's Spray Inhalant for Poultry, 10 1-pound packages of Barker's Hog Round Worm Powder, and 10 1-pound packages of Barker's Poultry Round Worm Powder, at Cologne, N. J. It was alleged in the libels that the articles had been shipped on or about November 24 and December 1, 1943, from Philadelphia, Pa., by Barker, Moore and Mein Co.

The Poultry Powder was labeled as containing the following minerals: Magnesium sulfate, dried iron sulfate, potassium nitrate, sulfur, sodium chloride, iodine, potassium iodide, calcium carbonate, iron oxide, magnesium carbonate, sodium hydrosulfite, sodium bicarbonate, partially defluorinated superphosphate, manganese carbonate, copper carbonate, cobalt chloride, zinc chloride, and nickel chloride; and the following vegetable materials: Asafetida, fenugreek, ginger, pennyroyal, black pepper, old process linseed cake meal, mustard bran, cocoa meal, calumba root, including 13 percent protein, $3\frac{1}{2}$ percent fat, and 16 percent fiber. Examination of a sample disclosed that the article was essentially of the composition indicated on the label.

The article was alleged to be misbranded in that certain statements on its label and in booklets entitled "Barker's Poultry Hand Book," which accompanied the article, were false and misleading, since they represented and suggested that the article was an appetizer and conditioner; that it would provide the essential minerals that help to keep the body fighting fit and the vegetable ingredients that assist with the smoothing and toning of the digestive operations; that it would save chicks; and that it would be efficacious in the treatment of diarrhea, pullorum disease, blue comb, enteritis, coccidiosis, cecal or bloody coccidiosis, intestinal or upper type coccidiosis, blackhead, roundworms and tape worms, respiratory disorders, and infectious fowl coryza (cold). The article would not fulfill the promises of benefit, nor would it be effective in the treatment of the conditions mentioned.

Analysis disclosed that the Spray Inhalant for Poultry was composed essentially of kerosene and phenols, such as creosote. The article was alleged to be misbranded in that certain statements on its label and certain statements and the design of the respiratory tract of a chicken, appearing in the booklet, were false and misleading, since they represented and suggested that the article would be effective in the treatment of respiratory disorders, infectious fowl coryza (cold), watery discharge from the nose and eyes, sticky eyelids, aspergillosis (brooder pneumonia), nutritional roup, and congested air passages. The article would not be efficacious in the treatment of those conditions. It was alleged to be misbranded further in that it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Analysis disclosed that the Hog Round Worm Powder consisted essentially of plant material (including tobacco), thymol, sand, and kamala. It was alleged to be misbranded in that the statements on its label which represented and suggested that it would be effective in the treatment of roundworms that infest hogs were false and misleading, since the article would not be effective for that purpose.

Analysis disclosed that the Poultry Round Worm Powder consisted essentially of tobacco, thymol, and sand. The article was alleged to be misbranded in that the statements on its label and in the above-named booklet, which accompanied the article, were false and misleading since they represented and suggested that the article would be efficacious in the treatment of any species of roundworms in poultry, whereas the article would not be efficacious for that purpose.

On March 1 and 15, 1944, no claimant having appeared, judgments of condemnation were entered and Poultry Powder, which had some feed value, was ordered delivered to a charitable institution. The other products were ordered destroyed.

1399. Misbranding of veterinary products. U. S. v. 51 Packages of Ger-Mo-Kill Poultry Bars, 21 Packages of Hog Wormer and Conditioner (Ger-Mo-Kill Pig and Hog Bars), and 21 Packages of Ger-Mo-Kill Sheep and Lamb Bars. Default decree of destruction. (F. D. C. No. 11989. Sample Nos. 8499-F, 8500-F, 40714-F, 40715-F.)

On March 17, 1944, the United States attorney for the District of Minnesota filed a libel against the above-mentioned products at Mountain Lake, Minn., alleging that the articles had been shipped by the Ger-Mo-Kill Chemical Co., from Colfax, Iowa, between the approximate dates of September 30, 1943, and January 20, 1944.

Examination disclosed that the Poultry Bars were red bars containing, chiefly, naphthalene, with small proportions of Epsom salt, copper sulfate, formaldehyde, kamala, creosote, and tobacco. The article was alleged to be misbranded in that certain statements in its labeling were false and misleading, since they represented and suggested that the article would be efficacious in the prevention and removal of worms in chickens and turkeys and in the treatment and prevention of coccidiosis, roup, bronchitis, colds, blackhead, and intestinal infections in chickens and turkeys, whereas the article, when used as directed, did not possess germicidal or worm-expelling properties for the prevention or treatment of any infectious or parasitic disease condition of poultry.

Examination disclosed that the Hog Wormer and Conditioner consisted of a green bar containing, chiefly, naphthalene, with small proportions of Epsom salt, copper sulfate, formaldehyde, creosote, and plant material. The article was alleged to be misbranded in that certain statements in its labeling were false and misleading, since they represented and suggested that the article would be efficacious in the treatment and prevention of necro and flu and in the prevention and destruction of worms in hogs, whereas the article did not possess germicidal or worm-expelling properties for the prevention or treatment of any infectious or parasitic disease conditions of hogs.

Examination of the Sheep and Lamb Bars disclosed that the article consisted essentially of naphthalene and small proportions of phenothiazine, Epsom salt, copper sulfate, and sodium bicarbonate. The article was alleged to be misbranded in that certain statements in its labeling were false and misleading, since they represented and suggested that the article possessed germicidal and worm-expelling properties and would be effective in the prevention and treatment of serious disease conditions of sheep and lambs and in the removal of any species of worms that infest sheep, whereas the article did not possess the properties claimed and would not be effective for the purposes recommended.

On January 8, 1945, the sole intervenor having withdrawn its claim and answer, judgment was entered ordering that the products be destroyed.

1400. Misbranding of Singer's Earth Crust Minerals. U. S. v. 20 Bags of Singer's Earth Crust Minerals, and a number of circulars. Default decree of forfeiture and destruction. (F. D. C. No. 12345. Sample No. 8446-F.)

On May 13, 1944, the United States attorney for the Western District of Wisconsin filed a libel against 20 100-pound bags of the above-named product and a number of circulars entitled "Singer's Earth Crust Minerals," at Bangor, Wis., alleging that the article and the circulars had been shipped on or about November 12, 1943, from Barrington, Ill., by the Chain of Lakes Duck Farm (E. Albert Singer).

Analysis of a sample showed that the article consisted essentially of clay or soil, calcium carbonate, a compound of phosphorus, and salt, including 13.4 percent calcium calculated as the metal, 1.3 percent phosphorus calculated as the element, and 12.6 percent salt.

The article was alleged to be misbranded in that certain statements on its label and in the accompanying circulars were false and misleading, since they represented and suggested that the article would be effective in keeping livestock and poultry healthy and in removing any species of worms from the intestines of livestock and poultry; that it would prevent poor digestion, loss of appetite, a run-down condition, and diseases in general; that it would lower mortality; that it would prevent the disease condition of poultry known as range paralysis; and that its use would save feeding costs, whereas the article, while it might furnish small amounts of certain food minerals, would not be efficacious for the purposes claimed.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 17, 1945, no claimant having appeared, judgment of forfeiture was entered and the product, together with the circulars, was ordered destroyed.

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PRODUCTS

N. J. No.	N. J. No.
Adolphus Peppermint, Adolphus Natural Organic Calcium Tablets, Adolphus Brand Calcium Tablets, Adolphus Brand Soybean Lecithin, Adolphus Brand Wheat Germ Oil, Adolphus Brand Improved B Complex, Adolphus Brand Mineral Capsules, Adolphus Brand Tar Shampoo -----	1357
Ambrozoin, Syrup of -----	1353
Antiseptic -----	1353
Azmarin Tablets -----	1381
B Complex Food Supplement, Improved -----	1357
Barker's Poultry Powder, Barker's Spray Inhalant for Poultry, Barker's Hog Round Worm Powder, and Barker's Poultry Round Worm Powder -----	1398
Bates vitamin preparations -----	1390
Benefax Vitamin B Complex, Benefax Vitamins A & D, and Benefax Multi Vitamins -----	1389
Boracic acid, powdered -----	1367
Broom Herb Laxative -----	1357
Bulko -----	1379
Calcium chloride -----	1364
Calcium pantothenate -----	1357
Calcium tablets -----	1357
Cod liver extract tablets -----	1369
Colon-ease Herb Tea -----	1379
Colusa Natural Oil and Colusa Natural Oil Capsules -----	1384
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Dextrose injection -----	1362, 1371, 1372
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Epinephrine hydrochloride, solution of -----	1366
Ger-Mo-Kill Poultry Bars, Ger-Mo-Kill Pig and Hog Bars (Hog Wormer and Conditioner), Ger-Mo-Kill Sheep and Lamb Bars -----	1399
Gestrone Chorionic Gonadotropin -----	1363
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Herb remedies -----	1354, 1357, 1379, 1385
Hog Wormer and Conditioner (Ger-Mo-Kill Pig and Hog Bars) -----	1399
Hormone, chorionic gonadotropic -----	1363
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Lactate—Ringer's Solution -----	1370
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Lemon, oil of -----	1368
Lippincott's Poultry Remedy -----	1395
Macu Brand Papaya Concentrate -----	1378
Magnesia, citrate of -----	1361
Mar-To-Ma Chick Rem, Mar-To-Ma Compound Powder, Mar-To-Ma Mycro Rem, and Mar-To Ma Cough & Cold Mixture -----	1397
Marvel Herb Tea -----	1385
Menthol inhalers -----	1393
Meskill's Special Compound No. 1-2-3 -----	1354
Miracle Electric Massager -----	1394
Munyon's Paw Paw Tonic -----	1386
Nue-Ovo -----	1380
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Ozolax -----	1357
Pal-Pinto Minerals -----	1355
Papaya concentrate -----	1378
Parker Herx Preparations, Junior Beginners Assortment -----	1391
Peppermint -----	1357
Potassium chloride -----	1365
Pso-Ridisal -----	1359
Ray-D Tablets -----	1377
Revitalizer -----	1396
Ringer's solution—lactate -----	1370
Rolle Garlic and Parsley with Honey -----	1387
Salugen -----	1353
Salvitae -----	1353
Sapomin -----	1379
Shampoo -----	1357
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Soothenklean -----	1379
Soybean lecithin -----	1357
Stover's, Dr., Golden Oil -----	1383
Stramonium leaves, powdered -----	1373
Sulfa-Ped -----	1360
Sulfa-Seb -----	1360
Three chlorides, isotonic solution of -----	1371
Udga Tablets -----	1358
Veterinary preparations -----	1395-1400
Vitamin preparations -----	1357, 1369, 1377, 1389, 1390

⁷ Seizure contested. Contains opinion of the court, findings of fact, and conclusions of law.

⁸ Seizure contested. Contains opinion of the court.

	N. J. No.		N. J. No.
Water, distilled.....	1362	Wheat germ oil.....	1357
double distilled.....	1374	Wiel Garlic Tablets.....	1388
Watkins Vitamins A-B-D-G Tablets, and Watkins Cod Liver Extract Tablets.....	1369	Willard's Tablets.....	^s 1356
		Wormex	1396

SHIPPERS AND MANUFACTURERS

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Anacin Co.: Benefax Vitamin B Complex, Benefax Vitamins A & D, and Benefax Multi Vitamins.....	1389	Klenk, F. A.: potassium chloride.....	1365
Azmarin Co.: Azmarin Tablets.....	1381	Kotalko Sales Co.: Kotalko.....	1392
Barker, Moore & Mein Co.: Barker's Poultry Powder, Spray Inhalant for Poultry, Hog Round Worm Powder, and Poultry Round Worm Powder.....	1398	Layman's Academy of Health. See Sherman, L. L.	
Bates Laboratories, Inc.: Bates vitamin preparations.....	1390	Lippincott, J. W.: Lippincott's Poultry Remedy.....	1395
Chain of Lakes Duck Farm (E. Albert Singer): Singer's Earth Crust Minerals.....	1400	Macu Fruit Products: papaya concentrate.....	1378
Cheplin Biological Laboratories: double distilled water.....	1374	Marvel Products Co., Inc.: Marvel Herb Tea.....	1385
Colusa Remedy Co.: Colusa Natural Oil and Colusa Natural Oil Capsules.....	1384	Merck & Co., Inc.: Doryl.....	1351, 1352
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Cutter Laboratories, Inc.: dextrose solution.....	1372	Miracle Products, Inc.: Miracle Electric Massager.....	1394
Dailey Mills, Inc.: Revitalizer, and Wormex.....	1396	National Magnesia Co.: citrate of magnesia.....	1361
Dartell Laboratories: DPS Formulae 80, 81, and 200.....	1382	New York Hair Co.: hair preparations.....	1391
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Ger-Mo-Kill Chemical Co.: veterinary products.....	1399	Sulfa-Seb and Sulfa-Ped.....	⁷ 1360
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Harvey Laboratories, Inc.: solution of epinephrine hydrochloride.....	1366	Penick, S. B., & Co.: powdered stramonium leaves.....	1373
Heller, Samuel: calcium chloride.....	1364	Phoenix Preparations: Munyon's Paw Paw Tonic.....	1386
Gestrone Chorionic Gonadotropin, and chorionic gonadotropic hormone.....	1363	Planet Products Co.: Dr. Stover's Golden Oil.....	1383
		Pro-Medico Laboratories, Inc.: calcium chloride.....	1364
		Gestrone Chorionic Gonadotropin, and chorionic gonadotropic hormone.....	1363
		Readyflask, Inc.: dextrose in distilled water, isotonic solution of three chlorides, and isotonic solution of sodium chloride.....	1371
		Research Laboratories, Inc.: Nue-Ovo.....	⁸ 1380
		Rolle Vegetable Juices, Inc.: Rolle Garlic and Parsley with Honey.....	1387

⁷ Seizure contested. Contains opinion of the court, findings of fact, and conclusions of law.⁸ Seizure contested. Contains opinion of the court.

	N. J. No.		N. J. No.
Sherman, L. L.:		Texas Carlsbad Water Co.:	
Colon-ease Herb Tea, Sapomin,		Pal-Pinto Minerals-----	1355
Bulko, and Sootherklean----	1379	Udga, Inc.:	
Singer, E. A. See Chain of Lakes		Udga Tablets-----	1358
Duck Farm.		Watkins, J. R., Co.:	
Speigelmire, T. H., & Son:		Watkins Vitamins A-B-D-G	
Mar-To-Ma Chick Rem, Com-		Tablets, and Watkins Cod	
pound Powder, Mycro Rem,		Liver Extract Tablets-----	1369
and Cough & Cold Mixture----	1397	Wiel Laboratories:	
Standard Synthetics, Inc.:		Wiel Garlic Tablets-----	1388
oil of lemon-----	1368	Willard Tablet Co.:	
Sulfa Products Co. of America		Willard's Tablets-----	⁸ 1356
(division of Nu-Basic Prod-		Winthrop Chemical Co., Inc.:	
ucts Co.):		sterile distilled water, and dex-	
Sulfa-Seb and Sulfa-Ped-----	⁷ 1360	trose solution-----	1362

⁷ Seizure contested. Contains opinion of the court, findings of fact, and conclusions of law.

⁸ Seizure contested. Contains opinion of the court:



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1401-1450

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., January 18, 1946.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1401. *Action to enjoin and restrain the interstate shipment of UtraJel. U. S. v. Pynosol Laboratories, Inc., Edwin G. Melich, and James J. Melich. Tried to the court. Injunction granted. (Inj. No. 54.)*

On October 7, 1943, the United States attorney for the Northern District of Illinois filed a complaint against the Pynosol Laboratories, Inc., a corporation, Chicago, Ill., Edwin G. Melich, and James J. Melich, president and secretary-treasurer, respectively, of the corporation, praying the institution of appropriate proceedings to permanently enjoin the defendants and all persons acting on their behalf from the introduction into interstate commerce of UtraJel, a misbranded drug. For the facts on which the complaint was based, see the court's findings of fact, set forth below.

On October 8, 1943, a temporary restraining order was issued, and on October 25, 1943, the case came on for hearing on the Government's motion for a preliminary injunction pendente lite. After consideration of the arguments of counsel, the court denied the motion and scheduled the case for trial on the question of grant-

*For labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, see No. 1402; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1403; failure to bear a label containing an accurate statement of the quantity of the contents, No. 1403; omission of, or unsatisfactory, ingredients statements, Nos. 1403, 1411, 1412, 1438, 1443; deceptive packaging, Nos. 1431, 1432, 1438; cosmetic, subject to the drug provisions of the Act, No. 1445.

ing a permanent injunction. The trial commenced on December 9, 1943, and at its conclusion the case was taken under advisement by the court. On January 6, 1944, the court entered the following findings of fact, conclusions of law, and order for judgment:

SULLIVAN, *District Judge*:

FINDINGS OF FACT

I

"The defendant, Pynosol Laboratories, Inc., is a corporation organized and existing under the laws of the State of Illinois and has its principal place of business and office in the city of Chicago, State of Illinois; the defendant, Edwin G. Melich, is president of said Pynosol Laboratories, Inc.; and the defendant, James J. Melich, is Secretary-Treasurer of said Pynosol Laboratories, Inc. The said defendants, Edwin G. Melich and James J. Melich, have for some years last past been president and secretary-treasurer, respectively, of said Pynosol Laboratories, Inc.

II

"The defendants, for several years last past, and presently, have been and now are introducing and delivering for introduction into interstate commerce and have been and now are causing the introduction and delivery for introduction into interstate commerce an article of drug upon the label of which appears, among other things, the legends 'UtraJel' 'Regular' or 'UtraJel' 'Mild'. Said drug has been shipped by said defendants from the aforesaid place of business in the city of Chicago, State of Illinois, or from Los Angeles, California, to, into, and through States other than the State of origin of the shipments.

III

"The drug is a semi-solid, amber-colored paste with an odor of pine oil. The quantities bearing the label legend 'Regular' consist essentially of castor oil, potash soap, pine oil, alkali combined iodine and water. The quantities bearing the label legend 'Mild', are essentially the same as the foregoing, except that the alkali combined iodine is not present. The formula and composition of said drug has not been consistent. The amount of castor oil potash soap in the drug has varied from 35.1 percent to 47.5 percent; that of pine oil from 10.3 percent to 25.2 percent; that of water from 34.9 percent to 44.5 percent; and in the drug labeled in part 'Regular', the alkali combined iodine has varied from 1.1 percent to 1.6 percent. Since for the purposes of this case there is no difference between 'UtraJel' 'Regular' and 'UtraJel' 'Mild', wherever hereinafter reference is made to 'Utra-Jel' or the 'drug' such reference will apply equally to both. Said drug is offered, among other things, for injection into the uterus for such purposes, among others, as a uterine evacuant, in terminating pregnancy at any stage of gestation, for inducing labor at term, in incomplete abortions, mis-carriages, and for removing retained portions of the products of conception and as a medicament in the treatment of minor infections of the cervix and cervical canal, cervical erosions, cystic cervix, cervicitis, Trichomonas vaginitis, and minor vaginal ulcerations.

IV

"In connection with the interstate distribution of the said drug, the defendants have distributed written, printed, and graphic matter in the form of circulars, containing suggestions and recommendations as to the usage, technique of use, specifying dosage, frequency and duration of administration. At times, the defendants have enclosed such circulars in retail cartons containing said drug and at times by enclosing the same in the shipping carton in which several of said retail cartons have been shipped. At the present time, the defendants are enclosing, and have so enclosed since July 15, 1942, in said retail cartons, a slip-in, the legend on which is as follows:

'DOCTOR: Directions are available ONLY TO THE MEDICAL PROFESSION. If you do not have a copy, make request on professional stationery or prescription blank, direct to

PNYNSOL LABORATORIES, INC.

Chicago, Ill., U. S. A.'

"In compliance with a doctor's request, referred to in the foregoing slip-in, for directions for the use of UtraJel, the defendants immediately dispatch, and have

for some time last past dispatched, such directions to the doctor requesting the same, by United States mail. The point of origin and the point of destination of the drug and the said circulars containing directions for use have been identical. The drug is valueless to a doctor unless he has available the defendants' directions for use, which set forth, among other things, the conditions for which the drug is offered, the manner and method of use and the dosages, duration and frequency of administration for the respective conditions with respect to which it is offered for use. The device employed by the defendants of enclosing the above-mentioned slip-in in the retail cartons containing the drug causes said circular to be incorporated by reference in the labeling of the drug.

V

"The name UtraJel which appears on the container and carton labels of the drug, and in the aforesaid circulars, and which name appears more specifically in Exhibits 'A' to 'J,' attached to plaintiff's complaint, represents and suggests that said drug is safe and appropriate for introduction into the uterus.

VI

"The aforesaid circulars, as well as various labels, more specifically Exhibits 'F' and 'G' attached to plaintiff's complaint, which have, from time to time, been affixed to containers and cartons of said drug, represent and suggest that said drug is an appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations, and as a uterine evacuant.

VII

"UtraJel is not an effective or appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations or as a uterine evacuant.

VIII

"UtraJel is not safe and appropriate for introduction into the uterus, but is unsafe and dangerous to health and has caused serious injuries. Among the specific injuries which have resulted from its use are extensive destruction of tissue, hemolysis, that is, the destruction of the red corpuscles of the blood, systemic poisoning affecting the heart, lungs, liver, spleen and kidneys, extensive hemorrhage and prolonged bleeding, peritonitis, pulmonary emboli, serious damage to various other internal organs, and the danger of increased susceptibility to infection.

IX

"The dangers to health and to living tissue hereinbefore enumerated in Paragraph VIII, for the most part, are due to the pharmacological action of the potash soft soap ingredient present in UtraJel, or any article of drug having potash soft soap as a base.

X

"The dangers to health hereinbefore enumerated in Paragraph VIII are present when UtraJel is used by licensed physicians or anyone, in any quantity, or for any duration, or with any frequency of usage, for the treatment of any conditions which prevail in the uterus.

XI

"Experiments were conducted with UtraJel on female animals. The results of these tests disclosed that the use of UtraJel on the experimental animals caused: respiratory difficulties upon injection, inflammation of all portions of the female genital tract, including vagina, cervix and uterus, necrosis or death of tissue described as ulceration of the vagina, necrosis of cervical tissue, necrosis of the lining of the uterine cavity and degeneration through the wall of the body of the uterus, resulting in perforation into the peritoneal cavity, the formation of scar tissue of the uterus resulting in permanent sterility, peritonitis with extensive adhesions, damage to blood vessels, to neighboring tissue, to the heart, lungs, and liver. Additional work on animal tissue showed that UtraJel is an hemolytic agent, that is, it destroys the red corpuscles of the blood. It is a recognized scien-

tific fact that the results obtained in such animal experimentation are comparable to the effects which will obtain if the drug is administered to humans.

XII

"The dangers to health, and life itself, inherent in the use of UtraJel, or any other drug having a potash soft soap for its base, or any base, with or without pine oil and with or without small quantities of alkali combined iodine, and water when used in or on the uterus and its ineffectiveness and inappropriateness when used for the treatment of minor cervical infections, cervical erosions, and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations and as a uterine evacuant, make essential the issuance of a permanent injunction restraining henceforth the interstate distribution of UtraJel for use in or on the uterus or in the vagina.

CONCLUSIONS OF LAW

I

"The Court is specifically authorized by Section 302 (a) of the Federal Food, Drug, and Cosmetic Act to restrain the introduction or delivery for introduction or the causing of the introduction or delivery for introduction into interstate commerce of a drug which is misbranded.

II

"Cause has been shown which warrants the issuance of a permanent injunction.

III

"The article of drug whether labeled in part 'UtraJel' 'Regular' or 'UtraJel' 'Mild' is a drug within the meaning of Section 201 (g) (3) of said Act.

IV

"The written, printed or graphic matter, in the form of circulars, distributed by the defendants enclosed either in retail cartons containing the drug or within shipping packages containing cartons containing the drug accompany said drug within the meaning of Section 201 (m) of the Act and hence constitute 'labeling'.

V

"The written, printed or graphic matter, in the form of a circular, dispatched by the defendants by mail in compliance with a request of a doctor is, as a result of the statement made in the slip-in enclosed in the said retail cartons, thereby incorporated by reference and constitutes labeling within the meaning of Section 201 (m) of the Act. The various labels which have been affixed by said defendants to the containers and cartons containing the drug and the said slip-in also constitute labeling within the meaning of said Section 201 (m).

VI

"Said drug is misbranded within the meaning of Section 502 (a) of the Act in that the name 'UtraJel' which appears in the labeling of the drug is misleading since said name represents and suggests that said drug is safe and appropriate for introduction into the uterus; whereas, in truth and in fact, it is not safe or appropriate for introduction into the uterus but is unsafe and dangerous and has caused serious and fatal consequences.

VII

"Said drug is misbranded within the meaning of Section 502 (a) of said Act in that the following statements appearing in the labeling of the drug:

(Tube and carton)

'UtraJel * * * For Cervical and Intra-Uterine use * * * For Specific and Non-Specific Infections of the Cervix and Cervical canal. * * *

'Utra-Jel * * * Indicated as an aid . . . In the treatment of minor infections of the cervix and cervical canal * * * as a uterine evacuant * * *

(Circulars)

'UTRAJEL * * * CERVICAL INFECTIONS AND CERVICAL EROSIONS (Minor). * * *
INFECTIONS OF THE CERVICAL CANAL (Minor). * * *
'CYSTIC CERVIX. * * * AS A UTERINE EVACUANT. * * *
'UTRAJEL * * * cervicitis, cervical erosions, Trichomonas vaginitis and
minor vaginal ulcerations * * * uterine evacuant * * *'

and words of similar import appearing in the labeling are false and misleading since said statements represent and suggest that UtraJel is an appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonas vaginitis, minor vaginal ulcerations, and as a uterine evacuant, whereas, in truth and in fact, said drug is not an effective or appropriate medicament for the treatment of minor cervical infections, cervical erosions and infections of the cervical canal, cystic cervix, cervicitis, Trichomonal vaginitis, minor vaginal ulcerations, or as a uterine evacuant.

VIII

"Said drug is misbranded within the meaning of Section 502 (j) in that it is dangerous to health when used in the uterus in any dosage or with any frequency or with any duration of administration prescribed, recommended or suggested in its labeling.

ORDER FOR JUDGMENT

"Upon the basis of the foregoing Findings of Fact and Conclusions of Law,
"It is hereby ORDERED, that a Permanent Injunction be entered accordingly,
with costs against the defendants."

On January 7, 1944, a permanent injunction was entered in accordance with the court's order.

1402. Misbranding of Grover Graham Remedy. U. S. v. S. Grover Graham Co., Inc., and Henry Wilson. Pleas of guilty. Corporate defendant fined \$250; individual defendant sentenced to 6 months' imprisonment and fined \$250. Execution of prison sentence suspended and individual defendant placed on probation for 1 year. (F. D. C. No. 12560. Sample No. 47774-F.)

On October 23, 1944, the United States attorney for the Southern District of New York filed an information against S. Grover Graham Co., Inc., Newburgh, N. Y., and Henry Wilson, president of the corporation, alleging shipment of a quantity of the above-named product from the State of New York into the State of Missouri on or about December 21, 1943.

Analysis of samples disclosed that the article consisted essentially of sodium bromide (approximately 8.5 grains per tablespoonful), magnesia, sodium bicarbonate, alcohol, chloroform, and water flavored with oil of peppermint and colored with a red dye.

The article was alleged to be misbranded (1) because of false and misleading statements on its label which represented and suggested that it would be efficacious in the cure, mitigation, treatment, and prevention of indigestion, dyspepsia, and other ailments due to imperfect and retarded functioning of the digestive organs, and that it might be taken with perfect safety as often as necessary; (2) in that certain information required by law to appear on the label was not placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the statement, "Sodium Bromide U. S. P. 3½%," would not be understood by the ordinary individual and would not inform that individual of the number of grains or other measure understood by him in a tablespoonful dose; (3) in that its labeling did not bear adequate directions for use, since the directions on the label, "Take a large tablespoonful after meals three times a day or whenever symptoms of indigestion occur * * * Dose should be half a wineglassful followed by another dose in a half hour if necessary. The remedy may be taken with perfect safety as often as necessary," provided for the consumption of an excessive amount of sodium bromide and placed no limitation on the number of doses to be taken daily, whereas consumption of an excessive amount of sodium bromide might be dangerous, and limitations on the number of doses of the article to be taken daily should be contained in the directions; (4) in that its labeling failed to warn that frequent or continued use of the article might lead to mental derangement, skin eruptions, and other serious effects, and that it should not be taken by those suffering from kidney disease; and (5) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recom-

mended, and suggested in the labeling, since the directions provided for the consumption of an excessive and dangerous amount of sodium bromide.

On November 20, 1944, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of \$250 on the corporate defendant. The individual defendant was sentenced to 6 months' imprisonment and fined \$250. Execution of the prison sentence was suspended, and the individual defendant was placed on probation for 1 year.

1403. Misbranding of Lax Laxative and Thyroid Tablets. U. S. v. 49 Envelopes of Lax Laxative and Thyroid Tablets (and 3 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 12669, 13067, 13179, 13831. Sample Nos. 64068-F, 68126-F, 68501-F, 68502-F, 79014-F, 79019-F.)

Between June 13 and September 28, 1944, the United States attorneys for the Eastern District of Michigan, the Northern and Southern Districts of Ohio, and the Middle District of North Carolina filed libels against the following quantities of the above-named product: 49 envelopes at Detroit, Mich., 49 envelopes at New Philadelphia, Ohio, 33 envelopes at Newark, Ohio, and 31 envelopes at Greensboro, N. C.; alleging that the article had been shipped between the approximate dates of May 11 and July 12, 1944, by the Carolina Chemical Co., Charleston, S. C.

Examination disclosed that there were in each envelope a number of pink tablets which contained plant drugs, including the laxative drug aloin, and a number of white or light-colored tablets which contained approximately $\frac{1}{2}$ grain of thyroid per tablet.

The article was alleged to be misbranded in that, by reason of the content of thyroid, it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Take one Lax Thyroid Tablet at bedtime, if you want to increase dosage you may take one before each meal * * * Lax Thyroid Tablets are intended to be used as a week by week treatment. Do not expect extraordinary results from taking one packing. * * * Loss of weight with Lax Thyroid Tablets does not usually start at once. It may take a few days or even a few weeks to get things started in the right direction * * * It takes a little time to experience the benefits of this treatment."

The article was alleged to be misbranded further (1) in that various portions were accompanied by a circular entitled "Lax Thyroid Tablets," which contained false and misleading representations that the article was a safe and effective remedy for obesity, and that it would produce greater vitality and a general feeling of well-being; and (2) in that portions of the article failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of the contents, or the common or usual name of each active ingredient and the name and quantity of thyroid contained in the article.

Between August 7 and December 12, 1944, no claimant having appeared, judgments were entered condemning the product and ordering its destruction.

1404. Misbranding of White's Cream Vermifuge. U. S. v. 32 Dozen Packages of White's Cream Vermifuge. Default decree of condemnation and destruction. (F. D. C. No. 12747. Sample No. 80008-F.)

On June 23, 1944, the United States attorney for the Western District of Tennessee filed a libel against 32 dozen packages of White's Cream Vermifuge at Memphis, Tenn., alleging that the article had been shipped on or about March 15, 1944, by James F. Ballard, Inc., from St. Louis, Mo.

Analysis of a sample disclosed that the article consisted essentially of oil of Chenopodium 3.1 percent, castor oil, and a small amount of peppermint oil.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling: (On carton and bottle label) "Dose: Children 3 to 5 years of age, half teaspoonful; * * * One dose morning and night for 2 or 3 days"; and (on circular in carton) "For children 3 to 5 years of age $\frac{1}{2}$ teaspoonful. * * * The regular dose should be given morning and evening, after meals, for 2 or 3 days." The labeling provided for an amount of oil of Chenopodium that is dangerous to the health of children 3 to 5 years of age.

The article was alleged to be misbranded further in that the following statements in the circular entitled "White's Cream Vermifuge," enclosed in the carton containing the article, were misleading: "There are numerous symptoms that indicate the presence of worms in children. Infestation of Round Worms in a child often affects the child's sleep, appetite, and well-being. At the first recogni-

tion of symptoms of Round Worms, use 'White's Cream Vermifuge'." The statements were misleading since they represented and implied that the symptoms mentioned are characteristic of roundworm infestation, whereas they are not characteristic of roundworm infestation.

On December 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1405. Misbranding of Aditis. U. S. v. 13 Bottles of Aditis. Default decree of destruction. (F. D. C. No. 13003. Sample No. 2557-F.)

On or about July 26, 1944, the United States attorney for the Western District of Missouri filed a libel against 13 bottles, each containing 100 capsules, of Aditis at Kansas City, Mo., alleging that the article had been shipped on or about July 15, 1942, from Masontown, Pa., by Jones-Hague, Inc.

Examination showed that each capsule of the article contained approximately 1 grain of thyroid and $\frac{1}{10}$ grain of barium iodide.

The article was alleged to be misbranded in that it contained thyroid and barium iodide in amounts which may have rendered it dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "One to three capsules daily."

On October 20, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1406. Misbranding of Prostlin, Amazine, and Polyvalent P. E. U. S. v. 4 Vials of Prostlin, 4 Vials of Amazine, and 3 Vials of Polyvalent P. E. Default decree of condemnation and destruction. (F. D. C. No. 13018. Sample Nos. 53744-F, 53746-F, 53747-F.)

On July 24, 1944, the United States attorney for the Southern District of California filed a libel against the above-mentioned articles at Los Angeles, Calif., alleging that they had been shipped on or about January 17 and March 29, 1944, from New York, N. Y., by the Lipoidal Laboratories.

The articles were alleged to be misbranded in that they were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in their labeling, quoted below, since they were for parenteral use and were not sterile but were contaminated with living microorganisms: (Prostlin) "Technique for Administration of Prostlin * * * Start with 1 cc. and repeat the dose every second day until all manifestations of prostatic disorders disappear. * * * Use an all glass syringe with a short sharp needle for administration. Sterilize by boiling"; (Amazine and Polyvalent P. E.) "Technique for Administration * * * Place ampoule in hot, not boiling, water, for five minutes. Use an all glass syringe, short sharp needle. Sterilize by boiling. * * * Use deltoid or gluteal areas for intramuscular injections. Give injections at body temperature. * * * Start with 6 minims and increase dose by 4 minims every other day until tolerance, which is indicated by slight rise in temperature followed by chill. Continue treatment until all symptoms disappear (4 to 6 weeks) * * * Dose for infants and children: Start with 2 minims and gradually increase until tolerance."

On August 24, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1407. Adulteration and misbranding of blue ointment and Cheri Hance Syrup and misbranding of Hance Compressed Tablets of Triple Bromides. U. S. v. Hance Bros. & White Co. Plea of nolo contendere. Fine, \$50. (F. D. C. No. 12575. Sample Nos. 50470-F, 50545-F, 50548-F.)

On December 20, 1944, the United States attorney for the Eastern District of Pennsylvania filed an information against the Hance Bros. & White Co., a partnership, Philadelphia, Pa., alleging shipment of the above-named products from the State of Pennsylvania into the State of New Jersey between the approximate dates of September 20 and October 6, 1943.

The blue ointment was alleged to be adulterated in that it purported to be and was represented as a drug recognized in the United States Pharmacopoeia, an official compendium, under the names "Blue Ointment" and "Mild Mercurial Ointment," but its strength differed from and its quality fell below the official standard, since that compendium provides that the article shall contain not less than 9 percent of mercury, whereas it contained mercury in amounts varying from

*See also No. 1402.

6.06 percent to 7.68 percent, and its difference in strength and quality from the standard was not plainly stated, or stated at all, on its label. The article was alleged to be misbranded in that the label statement, "Blue Ointment * * * U. S. P.," was false and misleading.

The Cheri Hance Sirup was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it purported and was represented to contain 8 grains of ammonium chloride per fluid ounce, whereas it contained not more than 5.83 grains of ammonium chloride per fluid ounce. It was alleged to be misbranded in that the label statement, "Each Fluid Ounce Contains: * * * Ammonium Chloride . . . 8 grs.," was false and misleading.

The Hance Compressed Tablets of Triple Bromides were alleged to be misbranded in that the labeling bore no directions for use.

On January 5, 1945, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$50.

1408. Misbranding of Emerson's Famous Medicine. U. S. v. 177 Bottles of Emerson's Famous Medicine. Default decree of condemnation and destruction. (F. D. C. No. 12708. Sample No. 73335-F.)

On June 19, 1944, the United States attorney for the Northern District of California filed a libel against 177 bottles of Emerson's Famous Medicine at Oakland, Calif., alleging that the article had been shipped from Kansas City, Mo., on or about February 17 and April 15, 1944, by the Emerson Medicine Co.

The labeling of the article included a circular contained in the cartons and entitled "Emerson's Famous Medicine," a card entitled "You'll Be Surprised," and a circular entitled "Your Horoscope," which latter contained the following statements, among other things: "Note the Medicinal Values given to the Roots, Barks and Herbs used in Emerson's Famous Medicine. Honduras Sarsaparilla, U. S. P.—Alterative, Depurative (Purifying the Blood), Cleansing. Yellow Dock, N. F.—Depurative (Purifying the Blood) Cleansing, Anti-Scorbutic. Prickly Ash Bark, N. F.—Alterative Tonic. * * * Burdock, N. F.—Diuretic. Stillingia, N. F.—Diuretic, Resolvent. Dandelion, N. F.—Hepatic, Stimulant Tonic. Poke Root, N. F.—Alterative. Mandrake, U. S. P.—* * * Hepatic, Emmenagogue. Liverwort Leaves—Demulcent, Pectoral."

Examination of a sample disclosed that the article contained, per tablespoonful, 2.66 grains of sodium salicylate, 0.27 grain of potassium iodide, and small proportions of extracts of plant drugs, including a laxative drug such as aloë. Water constituted approximately 96.8 percent of the preparation.

The article was alleged to be misbranded in that certain statements in the labeling and in the accompanying circulars were false and misleading in that they represented and suggested that the article was a harmless prescription for the treatment of muscular aches and pains, inorganic, rheumatic, and neuralgic aches and pains, indigestion, a tired, run-down feeling, constipation, bad breath, biliousness, sick headache, rheumatism, pimples and blotches, gas on the stomach, acid stomach, nervousness, sleeplessness, liver trouble, sciatica, and neuritis; and that the roots, barks, and herbs contained in the article possessed the medicinal properties ascribed to them. The article was not a harmless prescription; it would not be efficacious in the treatment of the conditions named; and the roots, barks, and herbs mentioned did not possess the medicinal properties ascribed to them, or they were present in the preparation in such small proportions as to be negligible.

The article was alleged to be misbranded further in that the statement on the carton and bottle labels, "Contains Honduras sarsaparilla, yellow dock, burdock, prickly ash bark, * * * liverwort leaves, * * * stillingia, dandelion, gentian root, * * * potassium iodide," was misleading in that it implied that the ingredients named were therapeutically active constituents of the article, and that they contributed to its medicinal effects, whereas they were not therapeutically active constituents and did not contribute to the medicinal effects of the article. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings, since the warning in the labeling against use "in cases of severe abdominal pains, vomiting, nausea or other symptoms of appendicitis" did not serve to warn against use when there was *any* pain, vomiting, nausea, or other symptoms of appendicitis; and since there was no warning to the effect that frequent or continued use of the article, which was essentially a laxative, might result in dependence upon laxatives to move the bowels.

On August 22, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1409. Misbranding of Konjola. U. S. v. 33¾ Dozen Bottles of Konjola. Decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 12045. Sample No. 29545-F.)

On March 22, 1944, the United States attorney for the Southern District of California filed a libel against 33¾ dozen bottles of Konjola at Los Angeles, Calif., alleging that the article had been shipped on or about January 4 and 17, 1944, by Konjola, Inc., from Buffalo, N. Y.; and charging that it was misbranded.

Examination showed that the article consisted essentially of water, with extracts of plant materials, including a laxative plant drug, glycerin, pepsin (approximately 0.16 gram per 100 cc.), compounds of iron (equivalent to 0.016 gram iron per 100 cc.), calcium, manganese, and a salicylate.

The article was alleged to be misbranded (1) in that certain statements in the labeling were false and misleading since they represented and implied that the article would be effective for digestive conditions, run-down conditions, simple anemia, rheumatism, and neuritis; that it contained sufficient iron or pepsin to be effective as a tonic or digestive aid; and that the article was more than a laxative, whereas the article would not be effective for such purposes and was merely a laxative; (2) in that its labeling failed to bear adequate directions for use, since the directions appearing on the label provided for the continued administration of a laxative; and (3) in that its labeling did not warn against use when *any* symptoms of appendicitis were present but limited abdominal pains to "severe continued abdominal pains."

On September 18, 1944, judgment was entered *nunc pro tunc* as of April 19, 1944, condemning the product and ordering that it be released under bond to be relabeled under the supervision of the Food and Drug Administration.

1410. Misbranding of Special Pills and Dean Pills. U. S. v. 30,000 Pills. Default decree of condemnation and destruction. (F. D. C. No. 12887. Sample No. 59087-F.)

On July 6, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 30,000 pills at Lancaster, Pa., alleging that the article had been shipped on or about December 10, 1940, by Strong, Cobb & Co., Inc., from Cleveland, Ohio. The greater portion of the article was contained in the original shipping drum, labeled, in part, "Special Pills—SC Pink," and the remainder of the article had been repacked in packages labeled, in part, "The Dean Formerly Madam Dean Pills."

Examination of samples showed that the article contained a laxative plant drug, such as aloes, ferrous sulfate, quinine sulfate, and other plant drugs.

The article was alleged to be misbranded in that it was essentially a laxative, and its labeling failed to warn that it should not be used in cases of nausea, vomiting, abdominal pain, and other symptoms of appendicitis; and that frequent or continued use might result in dependence upon a laxative to move the bowels.

On August 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1411. Misbranding of Special Pills and Dean Pills. U. S. v. 26,000 Pills. Default decree of condemnation and destruction. (F. D. C. No. 12887. Sample No. 51086-F.)

On July 6, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 26,000 pills at Lancaster, Pa., alleging that the article had been shipped on or about May 3, 1944, by Frederick Stearns & Co., from Detroit, Mich.

The greater portion of the article was contained in the original shipping drum, labeled, in part, "Special Pills—Oval G. C. Black"; and the remainder of the article had been repacked in packages labeled, in part, "The Dean Formerly Madam Dean Pills * * * The United Medical Company Lancaster, Pa." Examination of samples showed that the article contained a laxative plant drug, such as aloes, ferrous sulfate, quinine sulfate, and other plant drugs.

The article was alleged to be misbranded (1) in that it was fabricated from two or more ingredients, and its labeling failed to bear the common or usual name of each active ingredient; (2) in that its labeling failed to bear adequate directions for use; and (3) in that the article was essentially a laxative, and its labeling failed to warn that it should not be used in cases of nausea, vomiting, abdominal pain, and other symptoms of appendicitis; and that fre-

quent or continued use might result in dependence upon a laxative to move the bowels.

On August 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1412. Misbranding of Testilon. U. S. v. 980 Bottles and 1,351 Bottles of Testilon. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 12650. Sample Nos. 67084-F to 67086-F, incl.)

On or about June 20, 1944, the United States attorney for the Western District of Missouri filed a libel against 980 bottles, each containing 100 tablets, and 1,351 bottles, each containing 20 tablets, of Testilon at North Kansas City, Mo., alleging that the article had been shipped from Cleveland, Ohio, by Oxford Products, Inc., between the approximate dates of March 3 and April 19, 1944.

The article was labeled in part: "Testilon Each tablet contains Vitamin B₁ 666 U. S. P. Units Yohimbin Hydr. 0.005 Grams Orchic Substance 0.05 Grams Calcium Glycero Phosphates 0.15 Grams Sodium Glycero Phosphates 0.15 Grams Nux Vomica 0.03 Grams Vitamin Guild of America Division of Oxford Products, Inc. Manufacturing Chemists Cleveland, Ohio." Examination indicated that the article possessed the composition declared on its label.

The article was alleged to be misbranded (1) in that the label statements, "Testilon * * * Dosage—2 to 3 tablets depending upon age and severity of case * * * When desired effect is reached discontinue use," were false and misleading since such statements represented and suggested that the article was effective as a sex restorer, whereas it was not effective for that purpose; (2) in that the label statement, "Each Tablet Contains * * * Orchic Substance 0.05 Grams," was misleading since it failed to reveal the fact, material in light of such statement, that orchic substance possesses no therapeutic activity when taken by mouth; (3) in that its label failed to bear the name and quantity or proportion of strychnine contained in the article; and (4) in that its label failed to warn that, in view of the yohimbine hydrochloride present, the article should not be taken by those suffering from heart disease, high blood pressure, and kidney disease; that the product containing nux vomica may be dangerous, especially when used by elderly persons; and that use of a product containing yohimbine hydrochloride should be discontinued if stomach disturbance, nausea, vomiting, vertigo, or fainting occur.

On April 4, 1945, the case having been removed to the Northern District of Illinois, and Oxford Products, Inc., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1413. Misbranding of Gallusin. U. S. v. 17 Boxes of Gallusin. Default decree of condemnation and destruction. (F. D. C. No. 13113. Sample No. 67673-F.)

On August 2, 1944, the United States attorney for the Eastern District of Tennessee filed a libel against 17 boxes of Gallusin at Knoxville, Tenn., alleging that the article had been shipped on or about March 29 and July 1, 1944, from New York, N. Y., by the Sumlar Co.

Examination showed that the article contained laxative drugs including phenolphthalein.

The article was alleged to be misbranded (1) because of false and misleading statements on its label and in accompanying circulars, entitled "The Verdict of the Jury" and "Good News," regarding its efficacy in the treatment of disorders of the gall bladder, stomach, liver, and intestinal tract; and (2) in that its labeling failed to bear adequate warnings against unsafe methods or duration of administration, since the directions provided for habitual use.

On October 7, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1414. Action to enjoin interstate shipment of adulterated and misbranded drugs. U. S. v. Associated Laboratories, Inc., Samuel Goodman, and Benjamin Ross. Permanent injunction granted. (Inj. No. 71.)

On September 13, 1944, the United States attorney for the Eastern District of Pennsylvania filed a complaint against the Associated Laboratories, Inc., Philadelphia, Pa., and Samuel Goodman and Benjamin Ross, president and secretary-treasurer of the corporation, respectively, alleging that the defendants for several years past and at that time had been and were introducing and deliver-

ing and causing the introduction and delivery for introduction into interstate commerce of various drugs found to be in violation of the law.

The complaint alleged further that the defendants had prepared and shipped in interstate commerce quantities of ampuls of solution of sodium citrate that showed a serious shortage of sodium citrate; ampuls of solution of colchicine salicylate and iodide that contained less than 50 percent of the declared amount of salicylate and iodide; sterile solution of strontium bromide that contained mold and yeast and was contaminated with foreign particles; liver extract iron vitamin B₁₂ that was 90 percent deficient in its vitamin B₁₂ content; sterile solution of dextrose and sterile solution of calcium gluconate that contained undissolved material; and sterilized double distilled water that contained undissolved material and pyrogens. It was charged that each of the products so prepared and shipped was adulterated, and that the liver extract was also misbranded.

The complaint alleged further than an information charging the shipment in interstate commerce of a quantity of an adulterated and misbranded drug was filed against the corporation on December 30, 1942; and that a plea of nolo contendere was entered on behalf of the corporation, and a fine of \$100 was imposed. It was alleged further that since March 1941, numerous investigations of the manufacturing plant of the defendants and analyses of samples of products manufactured by them had been made by the Food and Drug Administration. The analyses disclosed the existence of insanitary conditions and the presence of filth, dust, animal excreta, and other foreign matter in and around the place of manufacture and packing and in and around the raw materials and substances out of which the drugs were manufactured, prepared, and packed for shipment; that inefficiency and intolerable drug manufacturing practices and control procedures existed where the utmost of efficiency should have prevailed to insure the integrity of drugs, some of which are hypodermically administered; that there was lack of proper facilities for filling and sealing ampuls in order to preclude contamination with foreign filth, fever-producing substances, and pathogenic organisms; and that dangerous laxity in identification of stored raw materials and drugs in process of manufacture, and other objectionable practices and conditions, existed in the plant.

The complaint alleged further that the defendants, unless restrained by the court, would continue to introduce and offer for introduction into interstate commerce adulterated drugs; and prayed that the defendants be perpetually enjoined from doing so; and further prayed that a preliminary injunction be granted, restraining the defendants during the pendency of the action.

On September 13, 1944, the court entered an order to show cause why, pending the outcome of the action, the defendants should not be enjoined and restrained. On October 4, 1944, the defendants having consented to the entry of a final decree, a permanent injunction was entered, as prayed in the complaint.

1415. Action to enjoin and restrain distribution of adulterated and misbranded drugs. U. S. v. J. L. Hopkins & Co. Consent decree granting injunction. (Inj. No. 69.)

On July 20, 1944, the United States attorney for the Eastern District of New York filed a complaint against J. L. Hopkins & Co., a corporation, Brooklyn, N. Y., alleging that on or before May 25, 1944, and thereafter, the defendant had been introducing and delivering for introduction into interstate commerce certain drugs that were adulterated in that they consisted in whole or in part of filthy substances; and in that they had been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. The complaint prayed that the defendant be enjoined and restrained forever from distributing adulterated or misbranded drugs in interstate commerce.

On July 20, 1944, the court issued a temporary restraining order and an order to show cause why a preliminary injunction should not be entered. On November 16, 1944, the defendant and the Government having consented to the entry of a decree, judgment was entered enjoining and restraining the defendant for a period of 6 months from committing the acts complained of. The court retained jurisdiction for the purpose of enforcing or modifying the decree, or for the purpose of granting additional or supplemental relief.

1416. Adulteration of granulated wild cherry bark and ground buckthorn bark. U. S. v. 2 Barrels of Granulated Wild Cherry Bark and 1 Bag of Ground Buckthorn Bark. Decree of condemnation. Products ordered destroyed. (F. D. C. No. 13090. Sample Nos. 77418-F, 77419-F.)

On August 3, 1944, the United States attorney for the Southern District of New York filed a libel against 2 barrels, each containing approximately 213 pounds,

of granulated wild cherry bark and 1 bag, containing approximately 100 pounds, of ground buckthorn bark at New York, N. Y., alleging that the articles had been shipped on or about February 15 and March 30, 1944, by S. B. Penick & Co., from Jersey City, N. J.

The articles were alleged to be adulterated (1) in that they consisted in whole or in part of filthy substances by reason of the presence, in the wild cherry bark, of insect parts, mites, insect excreta, and rodent hairs and, in the buckthorn bark, of insect parts, mites, and rodent hair fragments; (2) in that the articles had been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth; and (3) in that they purported to be and were represented as wild cherry bark and buckthorn bark, drugs the names of which are recognized in official compendia, the United States Pharmacopoeia and the National Formulary, respectively, but their quality and purity fell below the standards set forth in such compendia, since they were contaminated with filth.

On April 11, 1945, the sole intervenor having withdrawn its claim and answer, judgment of condemnation was entered, and the products were ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1417. Adulteration of triple distilled water. U. S. v. The Diarsenol Co., Inc.
Plea of guilty. Fine, \$1,050. (F. D. C. No. 12587. Sample Nos. 23487-F, 23665-F, 23734-F.)

On November 9, 1944, the United States attorney for the Western District of New York filed an information against the Diarsenol Co., Inc., Buffalo, N. Y., alleging shipment of quantities of triple distilled water between the approximate dates of July 3 and August 21, 1943, from the State of New York into the State of New Jersey.

The article was alleged to be adulterated in that, by reason of the fact that it was dispensed as a vehicle, solvent, or diluent for a substance to be administered parenterally, it purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium; but its quality and purity fell below the standard set forth therein, since it contained pyrogens and undissolved material; and its difference in quality and purity from the official product was not plainly stated, or stated at all, on its label. The article was alleged to be adulterated further in that pyrogens and undissolved material had been mixed and packed with it so as to reduce its quality.

On January 2, 1945, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$350 on each of 3 counts, a total fine of \$1,050.

1418. Adulteration of triple distilled water. U. S. v. 9 Cartons and 48 Boxes of Triple Distilled Water (and 3 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 13286, 14137, 14484, 14510. Sample Nos. 62001-F, 67995-F, 86952-F, 87510-F, 87511-F.)

Between August 22 and December 6, 1944, the United States attorneys for the District of Minnesota, the Northern District of Illinois, the Southern District of Alabama, and the Southern District of Ohio filed libels against the following quantities of triple distilled water: 9 cartons, each containing 100 ampuls, and 48 boxes, each containing 10 ampuls, at Minneapolis, Minn.; 84 boxes, each containing 10 ampuls, at Chicago, Ill.; 70 boxes, each containing 10 ampuls, at Mobile, Ala.; and 11 boxes, each containing 12 vials, at Springfield, Ohio. The libels alleged that the article had been shipped between the approximate dates of November 10, 1943, and April 5, 1944, by the American Medical Specialties Co., Inc., from New York, N. Y.

The article was alleged to be adulterated in that it purported to be water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since all lots were not clear but contained insoluble suspended material, and since the Minnesota lot did not meet the official test for pyrogens but contained pyrogenic substances.

Between October 26, 1944, and February 20, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

*See also Nos. 1407, 1414, 1416.

1419. Adulteration and misbranding of water for injection. U. S. v. 1,150 Ampuls of Water for Injection (and 3 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 12723, 13331, 13803, 14411. Sample Nos. 63531-F, 64020-F, 64045-F, 64059-F, 64202-F.)

Between June 22 and November 29, 1944, the United States attorneys for the Northern District of Georgia and the Eastern District of North Carolina filed libels against 2,305 ampuls of water for injection at Atlanta, Ga., and 6,840 ampuls of the same product at Raleigh, N. C., alleging that the article had been shipped or had been caused to be shipped by the Estro Chemical Co., from New York, N. Y., between the approximate dates of April 28 and July 26, 1944.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since all lots were contaminated with undissolved material, and since, in addition, two of the lots contained pyrogens.

The article in the Raleigh lot was alleged to be misbranded in that the label statement, "Water for Injection U. S. P. XII * * * Pyrogen Free," was false and misleading.

Between July 19, 1944, and February 2, 1945, no claimant having appeared, judgments of condemnation were entered, and the product was ordered destroyed.

1420. Adulteration of dextrose solution. U. S. v. 976 Vials of Dextrose Solution (and 7 other seizure actions against other lots of the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 12777, 12925, 12951, 12952, 12960, 13311, 13604, 13606. Sample Nos. 77585-F, 77586-F, 81714-F, 81715-F, 81772-F, 81780-F, 81981-F, 81983-F, 82246-F, 82263-F.)

Between June 26 and September 3, 1944, the United States attorneys for the Eastern, Southern, and Northern Districts of New York filed libels against the following quantities of dextrose solution: 976 vials at Central Islip, N. Y.; 370 vials at Wingdale, N. Y.; 788 vials at Brentwood, N. Y.; 86 vials at Brooklyn, N. Y.; 85 vials at Binghamton, N. Y.; 383 vials at New York, N. Y.; 214 vials at Kings Park, N. Y.; and 387 vials at Orangeburg, N. Y. It was alleged in the libels that the article had been shipped between the approximate dates of January 21 and June 29, 1944, from Philadelphia, Pa., by the Associated Laboratories, Inc. The article was labeled in part: "Sterile Solution 33.3% [or "50%"] Dextrose."

The article was alleged to be adulterated in that it purported to be dextrose injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not free from undissolved material.

Between August 2 and November 15, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1421. Adulteration of dextrose ampuls and sodium iodide ampuls. U. S. v. 38 Ampuls of Dextrose Solution and 6 Boxes of Ampuls of Sodium Iodide. Default decrees of condemnation and destruction. (F. D. C. Nos. 13186, 14015. Sample Nos. 63374-F, 63493-F.)

On or about August 11 and October 27, 1944, the United States attorney for the Northern District of Georgia filed libels against 38 ampuls of dextrose solution and 6 boxes, each containing 25 ampuls, of sodium iodide, alleging that the articles had been shipped on or about April 22, 1943, and April 19, 1944, by John Wyeth & Brother, Inc., from Philadelphia, Pa.

The articles were alleged to be adulterated in that they purported to be and were represented as dextrose injection and ampuls of sodium iodide, drugs the names of which are recognized in official compendia, the United States Pharmacopoeia and the National Formulary, respectively, and their quality and purity fell below the official standards since they were not free from undissolved material.

On September 14 and December 6, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1422. Adulteration of Intravenous Solution Ven-Dextrose and Intravenous Solution Physiologic Saline (Normal Salt). U. S. v. 82 Vials and 61 Bottles of Intravenous Solutions. Default decrees of condemnation and destruction. (F. D. C. Nos. 12697, 12718. Sample Nos. 60740-F, 60761-F.)

On June 20 and 26, 1944, the United States attorney for the Northern District of California filed libels against 61 100-cc. bottles and 82 50-cc. vials of intravenous solutions at San Francisco, Calif., alleging that the articles had been shipped on or about August 7, 1943, and February 1, 1944, from Denver, Colo., by the Intra Products Co.

The articles were alleged to be adulterated in that they purported to be dextrose injection and sterile isotonic solution of sodium chloride for parenteral use, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standard set forth therein since they were contaminated with undissolved material.

On August 22, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1423. Adulteration of lactate Ringer's solution, dextrose in physiological solution of sodium chloride, dextrose in lactate Ringer's solution, and Vitadex-B in Isotonic Solution of Sodium Chloride. U. S. v. 30 Packages of Dextrose in Lactate Ringer's Solution (and 2 other seizure actions against drugs for intravenous uses). Default decrees of condemnation and destruction. (F. D. C. Nos. 12667, 12769, 12849. Sample Nos. 55856-F, 55857-F, 55867-F, 73347-F.)

Between June 24 and August 1, 1944, the United States attorneys for the District of Colorado and the Western District of Washington filed libels against 30 packages of dextrose in lactate Ringer's solution at Denver, Colo., and 156 flasks of lactate Ringer's solution, 174 flasks of dextrose in physiological solution of sodium chloride, and 66 bottles of Vitadex-B at Seattle, Wash., alleging that the articles, which had been consigned by the Cutter Laboratories, Inc., had been shipped from Berkeley, Calif., between the approximate dates of September 15, 1943, and June 2, 1944.

The dextrose in physiological solution of sodium chloride was alleged to be adulterated in that it purported to be and was represented as dextrose and sodium chloride injection (dextrose and sodium chloride ampuls), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it contained undissolved material.

The other articles were alleged to be adulterated in that their purity and quality fell below that which they purported to possess, since they purported to be for intravenous uses but contained undissolved material, whereas they should have been free from undissolved material.

On July 5 and October 18, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1424. Adulteration of sodium citrate. U. S. v. 102 Cases (612 bottles) of Sodium Citrate (and 1 other seizure action against sodium citrate). Default decrees of condemnation and destruction. (F. D. C. Nos. 11521, 11828. Sample Nos. 55812-F, 55813-F, 55826-F, 55827-F.)

On January 22 and March 3, 1944, the United States attorney for the Western District of Washington filed libels against a total of 1,839 bottles of sodium citrate at Seattle, Wash., alleging that the article had been shipped between the approximate dates of September 10 and December 10, 1943, from Berkeley, Calif., by the Cutter Laboratories, Inc.; and charging that it was adulterated. The article was labeled in part: "Saffivacs (500 cc. Size) 70 cc. Sodium Citrate 2½% [or "Sediflask 50 cc. Sodium Citrate 4%"] W/V in Isotonic Solution of Sodium Chloride," or "Saffifuge 25 c.c. Sodium Citrate 4% W/V in Physiologic Solution of Sodium Chloride."

The article was alleged to be adulterated in that it purported to be anticoagulant solution of sodium citrate, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was cloudy and contained numerous small particles.

On August 19, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1425. Adulteration of posterior pituitary. U. S. v. 119 Vials of Posterior Pituitary. Default decree of destruction. (F. D. C. No. 13200. Sample No. 80846-F.)

On or about August 10, 1944, the United States attorney for the Western District of Missouri filed a libel against 119 vials of the above-named product at Kansas

City, Mo., alleging that the article had been shipped on or about July 14, 1944, by the S. E. Massengill Co., from Bristol, Tenn.-Va. The article was labeled in part: "10 cc. Size Injection Pituitary Posterior U. S. P. XII."

The article was alleged to be adulterated in that it purported to be and was represented as posterior pituitary injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

On October 20, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1426. Adulteration of posterior pituitary. U. S. v. 44 Vials of Posterior Pituitary. Default decree of condemnation and destruction. (F. D. C. No. 13246. Sample No. 15666-F.)

On or about August 19, 1944, the United States attorney for the Western District of Texas filed a libel against 44 vials of the above-named product at El Paso, Tex., alleging that the article had been shipped on or about July 6, 1944, from Los Angeles, Calif., by the Soltan Corporation. The article was labeled in part: "30 cc Vial Sterile Posterior Pituitary Obstetrical U. S. P. XI."

The article was alleged to be adulterated in that it purported to be posterior pituitary injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was contaminated with undissolved material.

On September 26, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1427. Adulteration and misbranding of compound tincture of benzoin. U. S. v. 196½ Dozen Bottles of Compound Tincture of Benzoin. Default decree of condemnation and destruction. (F. D. C. No. 13181. Sample Nos. 77236-F to 77238-F, incl.)

On August 5, 1944, the United States attorney for the Eastern District of New York filed a libel against 196½ 2-fluid ounce bottles of the above-named product at Brooklyn, N. Y., alleging that the article had been shipped on or about April 20 and 26 and June 5, 1944, by the Lorr Laboratories, from Paterson, N. J.

This article was colored with a mixture of coal-tar dyes consisting chiefly of D & C Brown No. 1 and F D & C Blue No. 1. Compound tincture of benzoin is recognized in the United States Pharmacopoeia and does not contain coal-tar colors.

The article was alleged to be adulterated in that a substance containing coal-tar dyes had been substituted in whole or in part for compound tincture of benzoin. It was alleged to be misbranded in that the designation "Compound Tincture of Benzoin" was false and misleading as applied to a product containing coal-tar dyes.

On November 15, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1428. Adulteration of calcium gluconate. U. S. v. 51 Vials of Calcium Gluconate. Default decree of condemnation and destruction. (F. D. C. No. 12872. Sample Nos. 75518-F, 75519-F.)

On July 5, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 51 vials, each containing 60 cc., of calcium gluconate at Cresson, Pa., alleging that the article had been shipped on or about October 18, 1943, and April 3, 1944, by the G. F. Harvey Co., from Saratoga Springs, N. Y.

The article was alleged to be adulterated in that it was a drug recognized in an official compendium, the United States Pharmacopoeia, but its purity and quality fell below the official standard since it was contaminated with undissolved material.

On August 8, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1429. Adulteration of vitamin B₁. U. S. v. 873 Vials of Vitamin B₁. Default decree of condemnation and destruction. (F. D. C. No. 12895. Sample No. 76296-F.)

On June 26, 1944, the United States attorney for the Eastern District of New York filed a libel against 873 vials of vitamin B₁ at Long Island City, N. Y., alleging that the article had been shipped on or about May 8, 1944, by Buffington's, Inc., from Worcester, Mass. The article was labeled in part: "Vitamin B₁ (Thiamin Chloride) * * * Intramuscular or Intravenous."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported to possess, since it was contaminated with undissolved material and was therefore unsuitable for intravenous or intramuscular administration.

On July 26, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1430. Adulteration and misbranding of eye dressing sets. U. S. v. 20,000 Cartons of Eye Dressing Sets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 12848. Sample No. 32942-F.)

On July 5, 1944, the United States attorney for the Northern District of New York filed a libel against 20,000 cartons of eye dressing sets at Binghamton, N. Y., alleging that the article had been shipped on or about June 14, 1944, by the A. E. Halperin Co., Inc., from Boston, Mass.

Examination disclosed that in each of the cartons of the article there were three eye pads, each of which were individually packed and labeled, in part, "Sterilized Gauze Covered Cotton Eye Pad."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, since it was not sterile but was contaminated with living micro-organisms. It was alleged to be misbranded in that the statement on the label, "Sterilized," was false and misleading.

On November 8, 1944, A. E. Halperin Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for reesterilization under the supervision of the Food and Drug Administration.

1431. Adulteration and misbranding of Gauztex. U. S. v. 23 Dozen Packages of Gauztex (and 2 other seizure actions against Gauztex). Default decrees of condemnation and destruction. (F. D. C. Nos. 12910, 13900, 14786. Sample Nos. 59361-F, 80917-F, 90423-F.)

Between July 11 and December 19, 1944, the United States attorneys for the Eastern District of Wisconsin, the Eastern District of Tennessee, and the Western District of Missouri filed libels against the following quantities of Gauztex: 23 dozen packages at Milwaukee, Wis.; 64 dozen packages at Knoxville, Tenn.; and 58 dozen packages at North Kansas City, Mo. It was alleged that the article had been shipped from Chicago, Ill., by General Bandages, Inc., between the approximate dates of May 3 and October 4, 1944.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported to possess, since it was a bandage and was not sterile.

The article was alleged to be misbranded in that the label statement, "Medicated with Mercuric Chloride Antiseptic Approx. 1/8000 By Weight," was false and misleading since the article contained between $\frac{1}{4}$ and $\frac{3}{8}$ of that amount of mercuric chloride. The article in the Milwaukee lot was alleged to be misbranded further in that its container was so made and filled as to be misleading, since the carton was larger than was necessary to hold the amount of bandage contained therein.

Between August 10, 1944, and January 26, 1945, no claimant having appeared, judgments were entered condemning the product and ordering its destruction.

1432. Adulteration and misbranding of gauze. U. S. v. 56 Packages and 109 Packages of Gauze. Default decree of condemnation and destruction. (F. D. C. No. 12719. Sample No. 78666-F.)

On June 23, 1944, the United States attorney for the Northern District of Indiana filed a libel against 56 packages, $1\frac{1}{2}$ inches by 5 yards size, and 109 packages, 2 inches by 10 yards size, of gauze at Whiting, Ind., alleging that the article had been shipped on or about April 12, 1944, by Radecke & Co., Chicago, Ill. The article was labeled in part: "Radeco Cohesive Gauze."

Examination of samples showed that the article was not sterile but was contaminated with living micro-organisms. The conditions under which such articles are used necessitate sterility. Consumers expect an item of this character to be sterile, and the United States Pharmacopoeia requires roller gauze bandage, adhesive absorbent gauze, and similar articles, to be sterile.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, since it was a bandage and was not sterile.

The article was alleged to be misbranded in that the label statement, "Sterilized," appearing on some of the packages, was false and misleading; and in that its container was so made, formed, and filled as to be misleading, since the cartons for both sizes were materially larger than was necessary to hold the amount of bandage contained therein.

On November 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1433. Adulteration and misbranding of prophylactics. U. S. v. 12 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 12901. Sample No. 78161-F.)

On July 8, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 12 gross of prophylactics at Philadelphia, Pa., alleging that the article had been shipped on or about January 4, 1944, from New York, N. Y., by the Goodwear Rubber Co., Inc. The article was labeled in part: "Kaps * * * Cap Type Rubber Glans Sheaths."

Examination of samples disclosed that the article was defective in that it contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess.

The article was alleged to be misbranded in that the labeling statements quoted below were false and misleading as applied to an article that contained defects such as holes: (Cartons) "Each One of These Kaps Has Been Filled To At Least Ten Times Its Normal Capacity With Water Under Pressure; Then Squeezed and Kneaded In An Effort To Make a Hole Appear—Even where Only A Weak Spot May Have Existed Before. Insist On Water-Tested Merchandise"; and (printed slip enclosed in small carton) "Notice: The Enclosed Sheath Has Been 'Water Tested' By Expanding Under Water Pressure To At Least Ten Times Its Normal Capacity—Then Examining Closely For Any Detectable Leak."

The article was alleged to be misbranded further in that the statement in its labeling, "Cap Type Rubber Glans Sheaths," was misleading since it failed to reveal the material fact that even those units which were not defective could not be depended on to protect against all types of venereal disease.

On August 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1434. Adulteration and misbranding of prophylactics. U. S. v. 29 Gross and 6 Gross of Prophylactics. Default decrees of condemnation and destruction. (F. D. C. Nos. 12962, 13827. Sample Nos. 81619-F, 81686-F.)

On July 18 and September 29, 1944, the United States attorney for the Southern District of New York filed libels against 35 gross of prophylactics at New York, N. Y., alleging that the article had been shipped on or about June 30 and September 11, 1944, by the Rubber Research Products Corporation, Hoboken, N. J.; and charging that it was adulterated and misbranded in essentially the same way as the article described in notices of judgment on drugs and devices, No. 1433. The article was labeled in part: "Kaps * * * Cap Type Rubber Glans Sheaths."

On August 5, and November 1, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1435. Adulteration and misbranding of prophylactics. U. S. v. 900 Cases (45,000 gross) of Prophylactics (and 4 other seizure actions against prophylactics). Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 13010, 13085, 13934, 13958, 14173. Sample Nos. 63492-F, 68748-F, 72477-F, 72478-F, 72491-F, 87502-F.)

Between July 24 and November 2, 1944, the United States attorneys for the Northern District of Georgia, the District of Minnesota, the Western District of Tennessee, and the Southern District of Indiana filed libels against the following quantities of prophylactics: 45,000 gross at Atlanta, Ga.; 198 gross at Minneapolis, Minn.; 4,920 gross at Memphis, Tenn.; and 49¼ gross at Spencer, Ind. It was alleged that the article had been shipped by the Killashun Sales Division, from Akron, Ohio, between the approximate dates of September 15, 1943, and August 22, 1944. The article was labeled in part: "Made from Genuine Liquid Latex. Mfd. by Shunk Latex Prod. Inc., Akron, Ohio," "Xcello's Prophylactics," "Genuine Latex Apris Prophylactics Manufactured by the Killian Mfg. Co. Akron, Ohio," "Silver-Tex Prophylactics," or "Texide Rubber Sheaths."

Examination of samples disclosed that the article was defective in that it contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. With the exception of the Indiana lot, the article was alleged to be misbranded because of false and misleading statements in its labeling regarding its efficacy in the prevention of disease.

On July 31, 1944, W. H. Reed and Co., Atlanta, Ga., claimant, having admitted the allegations of the libel against the Georgia lot, judgment of condemnation was entered and the product was ordered released under bond, conditioned that the product be tested and that the unfit portion be destroyed under the supervision of the Food and Drug Administration. Between September 11 and December 29, 1944, no claimant having appeared for the other lots, judgments of condemnation were entered and the product was ordered destroyed.

1436. Adulteration and misbranding of prophylactics. U. S. v. 46½ Gross of Prophylactics. Default decree of destruction. (F. D. C. No. 13182. Sample No. 87509-F.)

On August 8, 1944, the United States attorney for the District of Minnesota filed a libel against 46½ gross of prophylactics at Minneapolis, Minn., alleging that the article had been shipped on or about July 20, 1944, by the Standard Drug Co., from Chicago, Ill. The article was labeled in part: "Silver-Tex Prophylactics."

Examination of samples disclosed that the article was defective in that it contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded in that the label statement, "Prophylactics," was false and misleading as applied to an article that contained holes.

On October 2, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1437. Adulteration and misbranding of prophylactics. U. S. v. 49½ Gross, 161½ Gross, and 92½ Gross of Prophylactics. Default decrees of destruction. (F. D. C. Nos. 12686, 12760, 13053. Sample Nos. 40152-F, 40436-F, 40507-F, 87401-F.)

Between June 14 and July 25, 1944, the United States attorney for the District of Minnesota filed libels against 303½ gross of prophylactics at Minneapolis, Minn., alleging that the article had been shipped between the approximate dates of February 14 and April 26, 1944, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo., and Kansas City, Mo. The article was labeled in part: "Peacocks," or "Ultrex Platinum."

Examination of samples showed that the article was defective in that it contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded in that the labeling statements, (49½-gross lot) "Air-Tested Each and Every Peacock Device is 'Scientifically Tested' by Special Process * * * an aid in preventing venereal disease Guaranteed Two Years Against Deterioration," (161½-gross lot) "Scientifically Tested * * * For Your Protection * * * Guaranteed Against Deterioration for Two Years," and (92½-gross lot) "Scientifically Tested by Special Process. * * * An Aid in Preventing Venereal Disease," were false and misleading as applied to an article containing holes.

Between July 26 and September 11, 1944, no claimant having appeared, judgments were entered ordering that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1438. Misbranding of Ceregen. U. S. v. 19 Dozen Packages of Ceregen. Default decree of condemnation and destruction. (F. D. C. No. 12710. Sample Nos. 35256-F to 35259-F, incl.)

On or about June 22, 1944, the United States attorney for the Southern District of Florida filed a libel against 19 dozen packages of Ceregen at Tampa, Fla., alleging that the article had been shipped by the Ulrici Medicine Co., Inc., from New York, N. Y., between the approximate dates of December 24, 1943, and February 23, 1944.

* See also Nos. 1401-1404, 1407-1409, 1412-1414, 1419, 1427, 1430-1437.

Examination of a sample showed that the article consisted of approximately 10 percent alcohol, 5 percent nonvolatile matter, and 85 percent water. The nonvolatile matter included phosphates and glycerophosphates of sodium, potassium, and iron; material derived from *nux vomica*, including strychnine, caffeine, sugar, glycerin, and caramel. Each 100 milliliters of the article contained approximately 3 milligrams of iron, 60 milligrams of caffeine, and 2 milligrams of strychnine.

The article was alleged to be misbranded in that certain statements on its label and in an accompanying circular entitled "Ceregen" were false and misleading since they represented and suggested that the article would be efficacious in toning the system, supplying deficiencies of iron, phosphorus, and other salts, and in treating physical exhaustion and nervous hyposthenia; and that all ingredients of the article were of the standard of purity and strength established by the United States Pharmacopoeia. The article was not effective to fulfill the promises of benefit stated and implied, and some of the ingredients, including the glycerophosphates of sodium, potassium, and iron, are not recognized by the United States Pharmacopoeia.

The article was alleged to be misbranded further (1) in that the statement on its labels, "A preparation containing phosphates and glycerophosphates of sodium, potassium and iron in a balanced proportion," was misleading since the phosphates and glycerophosphates of sodium, potassium, and iron in the preparation were of no therapeutic significance; (2) in that its container was so made, formed, and filled as to be misleading, since the carton was materially taller than was necessary for the size of the bottle contained therein; and (3) in that the common or usual name of each active ingredient, required by law to appear on the label, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since fluidextract of *nux vomica*, the only therapeutically significant active ingredient contained in the article, was not named upon the bottle label, and upon the carton it was mentioned in a long list of other nonactive ingredients so as not to inform the purchaser that it was the sole therapeutically important active ingredient of the preparation.

On July 17, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1439. Misbranding of Lock's 9.12 Formula. U. S. v. 168 Packages of Lock's 9.12 Formula. Default decree of condemnation. Product ordered delivered to the National Zoological Park, for use as animal feed. (F. D. C. No. 13361. Sample No. 79299-F.)

On August 17, 1944, the United States attorney for the District of Columbia filed a libel against 168 packages of Lock's 9.12 Formula at Washington, D. C., alleging that the article had been shipped on or about August 2, 1944, by Lock's Laboratories, New York, N. Y.

Examination of a sample showed that the article consisted of approximately 63 percent of wheat germ with smaller proportions of other ingredients, including seaweed, gum karaya, and yeast.

The article was alleged to be misbranded in that certain statements in an accompanying leaflet entitled "Eat For Health" were false and misleading since they represented and suggested that use of the article would assure health to the user; that the article would supply 9 vitamins and 12 minerals for which the need in human nutrition has been demonstrated and which are not supplied, to the extent that they are needed, in the ordinary diet; that the vitamins A, B, C, D, E, G (or B₂), B₆, niacin, and calcium pantothenate would promote appetite and growth, digestion and assimilation of food, normal nerve health, and normal adrenal function, and would help to protect the eyes, ears, nose, and throat against infection, protect the body from nerve diseases and against infections of the respiratory tract, stimulate metabolic processes, and insure healthy blood vessels, gums, teeth, and skin; that those vitamins would prevent low resistance of the mucous membranes to cold infection, lowered resistance to skin infections, stones in kidneys and bladder, poor vision, tear duct infections, corneal ulcers, rough, dry skin, nervousness, irritability, dyspepsia, retarded growth, brain disturbance, heart disturbance, dry, scaly skin, lack of muscular tone, weakness, loss of weight and vigor, weakened blood capillaries, general tendency to bleeding, decreased red blood cells, tender joints (pain and swelling), cataracts, sallowness, pale complexion, anemia, spongy, swollen gums, tooth decay and defective teeth, low blood pressure, loss of appetite,

reduced adrenal secretion, peptic and duodenal ulcers, bone abscesses, lowered resistance to tuberculosis, bowlegs, sterility, digestive disturbances, dermatitis, pigmentation and thickening of the skin, soreness and inflammation of the tongue and mouth, diarrhea, colitis, nervous and mental disorders, secondary anemia, and dullness and loss of hair; and that the hair is nourished by sulfur, iodine, and silicon, the stomach by sulfur and vitamin B, the brain by manganese, phosphorus, and vitamins B and G, the gall bladder by sodium, the eyes by fluorine and vitamin A, the intestines by magnesium, the thyroid gland by iodine, the kidneys by magnesium, the teeth by calcium, silicon, and vitamin D, the adrenal gland by magnesium and vitamins A, B, C, and G, the throat by vitamin A, the blood stream by iron, oxygen, hydrogen, and vitamin A, the liver by chlorine, the muscles by potassium, and the heart by potassium and vitamins A and G. The use of the article would not assure health to the user; the article would not supply 9 vitamins and 12 minerals for which the need in human nutrition has been demonstrated and which are not supplied, to the extent that they are needed, in the ordinary diet; the vitamins A, B, C, D, E, G (or B₂), B₆, niacin, and calcium pantothenate would neither serve the purposes nor prevent the pathological conditions stated; and the parts of the body mentioned are not specifically nourished by the elements and vitamins enumerated.

The article was alleged to be further misbranded in that the label statements, "contain * * * Potassium, Sulphur, Sodium * * * Copper, Chlorine, Manganese, Zinc * * *," and "The minimum daily requirements of * * * Potassium, Sulphur, Sodium, * * * Copper, Chlorine, Zinc and Manganese have not yet been established for human nutrition," were misleading in the absence of a statement to the effect that those elements, to the extent that they may be needed in human nutrition, are supplied by the ordinary diet so that it is unnecessary to supplement the diet with preparations of them.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On October 25, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the National Zoological Park, for use as animal feed.

1440. Misbranding of Hall's Canker Remedy. U. S. v. 69 Bottles of Hall's Canker Remedy. Default decree of condemnation and destruction. (F. D. C. No. 13203. Sample No. 73739-F.)

On August 9, 1944, the United States attorney for the Southern District of California filed a libel against 69 3-ounce bottles of the above-named product at Los Angeles, Calif., alleging that the article had been shipped on or about April 27, 1944, from Salt Lake City, Utah, by the Hall's Canker Remedy.

Examination showed that the article consisted essentially of zinc sulfate, borax, sugars, and water.

The article was alleged to be misbranded in that the label statements, "Canker Remedy * * * aids in the treatment of Canker, Simple Sore Throat, and all minor mouth * * * Irritations * * * if the canker is not relieved, repeat dose as before. Most cases are usually remedied in nine doses," were false and misleading since the article would not be effective in the treatment of canker, simple sore throat, and all minor mouth irritations.

On August 31, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1441. Misbranding of Q-T Alternative—Nervine. U. S. v. 4¾ Dozen Bottles and 2¾ Dozen Bottles of Q-T Alternative—Nervine. Default decree of destruction. (F. D. C. No. 13174. Sample Nos. 66942-F, 66943-F.)

On or about August 21, 1944, the United States attorney for the Western District of Missouri filed a libel against 4¾ dozen 2-fluid ounce bottles and 2¾ dozen 4-fluid ounce bottles of the above-named product at Kansas City, Mo., alleging that the article had been shipped on or about February 26, 1943, from Cleveland, Ohio, by the Allied Pharmacal Co.

Analyses showed that the article consisted essentially of ammonium chloride approximately 6 grains per fluid ounce, gold and sodium chloride, and water.

The article was alleged to be misbranded in that the label statement "Alternative—Nervine" was false and misleading since the article was not an alternative and would have no effect on the nerves; and (2-fluid ounce size only) in that the label statement, "Each fluid ounce contains: Ammonium Chloride U. S. P. XI . . . 60 grains," was false and misleading since the article contained less than 60 grains of ammonium chloride per fluid ounce.

On October 21, 1944, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1442. Misbranding of rectal suppositories. U. S. v. 324 Boxes of Rectal Suppositories. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 12804. Sample No. 6076S-F.)

On June 26, 1944, the United States attorney for the Northern District of California filed a libel against 324 boxes, each containing 12 rectal suppositories, at San Francisco, Calif., alleging that the article had been shipped from Kansas City, Mo., by Wise's Kansas City Homeopathic Pharmacy between the approximate dates of February 5 and May 4, 1944.

Examination of a sample disclosed that the article consisted of a gelatin capsule containing oil of thuja, cocoa butter, and a green coloring matter.

The article was alleged to be misbranded in that the statement on its label, "For Relief of Rectal Trouble, Senile Hypertrophy, Prostatitis, Etc.," was false and misleading since the article contained no ingredient which would be effective in the relief of those conditions.

On August 11, 1944, Wise's Kansas City Homeopathic Pharmacy having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1443. Misbranding of Drefs' Preparation. U. S. v. 91½ Dozen Bottles of Drefs' Preparation. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 13073. Sample No. 33889-F.)

On July 26, 1944, the United States attorney for the Western District of New York filed a libel against 91½ dozen bottles, each containing 3 fluid ounces, of the above-named product at Buffalo, N. Y., alleging that the article had been shipped on or about February 3, 1944, from Philadelphia, Pa., by Hance Bros. & White Co. The article was labeled in part: "Drefs' Preparation for the Relief of the Symptoms of Whooping Cough Alcohol 16% Active Ingredients: Castanea * * * Distributed by Drefs' Remedies, Buffalo, N. Y."

Analysis disclosed that the article consisted essentially of alcohol, not more than 10.1 percent, and an extract of a plant drug such as chestnut.

The article was alleged to be misbranded (1) in that the statement on its label, "Preparation for the Relief of the Symptoms of Whooping Cough," was false and misleading since the article was not effective for the relief of those symptoms; and (2) in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of alcohol contained therein, since the label statement "Alcohol 16%" was incorrect.

On August 23, 1944, Ruth Adams, trading as Drefs' Remedies, Buffalo, N. Y., claimant, having admitted that the product was misbranded as alleged in the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1444. Misbranding of Leonardi's Injection No. 1 and Reno's New Tonic. U. S. v. 3 Dozen Packages of Leonardi's Injection No. 1 and 4 Dozen Packages of Reno's New Tonic. Default decree of forfeiture and destruction. (F. D. C. No. 13173. Sample Nos. 81634-F, 81635-F.)

On August 10, 1944, the United States attorney for the District of Puerto Rico filed a libel against 3 dozen packages of Leonardi's Injection No. 1 and 4 dozen packages of Reno's New Tonic at Ponce, P. R., alleging that the articles had been shipped on or about May 23, 1944, from New Rochelle, N. Y., by S. B. Leonardi and Co.

Examination showed that Leonardi's Injection No. 1 was a yellow-colored liquid having the odor of camphor. It was alleged to be misbranded in that the statements on its labels, "Leonardi's Injection No. 1 * * * Contains Berberine Sulphate Neutral Camphor—Boric Acid," and "Directions Use syringe holding about two teaspoonfuls and inject three or four times a day. Wash syringe out after injections. Keep bowels open and avoid fat meats, alcoholic stimulants and sexual intercourse," and similar directions in Spanish, were false and misleading since they represented and suggested that the article was effective as a treatment for gonorrhea, whereas it was not effective for that purpose.

Examination of Reno's New Tonic showed that it contained a compound of iron and plant material, including a laxative drug such as senna; that its iron content calculated as the metal was 35 milligrams per fluid ounce; and that 8 teaspoonfuls of the preparation would provide approximately 44

milligrams of iron. It was alleged to be misbranded in that the label statement, "Contains: Citro Chloride of Iron Sol. Aletris True Squaw Vine Berberis Aquifolium Black Haw Bark Saw Palmetto Berries Senna T. V.," and similar label statements in Spanish, were false and misleading since they created the impression that the article possessed tonic properties, and particularly tonic properties due to its iron content, whereas the article, when consumed as directed, would not be effective as a tonic because it yielded too little iron in such dosage to possess tonic properties, and the other ingredients possessed no tonic properties. It was alleged to be misbranded further in that the statement, "Reno's New Health Uterine Tonic," which was blown into the glass bottles, was false and misleading since use of the article would neither maintain the health of those who were healthy nor restore health to those who were unhealthy, and it would not act as a uterine tonic.

On November 1, 1944, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1445. Misbranding of hair tonic. U. S. v. 81 Bottles and 32 Bottles of Hair Tonic. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 12914. Sample Nos. 78223-F, 78224-F.)

On July 10, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 81 3½-fluid ounce bottles and 32 8-fluid ounce bottles of hair tonic at Philadelphia, Pa., alleging that the article had been shipped on or about April 10 and May 3 and 27, 1944, from New York, N. Y., by the Alpinol Corporation. The article was labeled in part: "Acqua * * * Chinina-Migone Tonico Per I Capelli Migone's Hair Tonic."

Analysis of samples showed that the article consisted essentially of alcohol and water, with small amounts of essential oils, a red coloring matter, and a trace of quinine.

The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and implied that the article contained a significant proportion of quinine; and that it was a hair tonic and would be efficacious in preventing dandruff and the loss of hair.

On August 2, 1944, the Alpinol Corporation, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

DRUGS FOR VETERINARY USE

1446. Misbranding of Coridene and Neol. U. S. v. The Gland-O-Lac Co. Plea of nolo contendere. Fine, \$150 and costs. (F. D. C. No. 12548. Sample Nos. 5667-F, 5668-F.)

On September 4, 1944, the United States attorney for the District of Nebraska filed an information against the Gland-O-Lac Co., a partnership, Omaha, Nebr., alleging shipment of quantities of the above-named products on or about December 12, 1942, from the State of Nebraska into the State of Iowa.

Analysis disclosed that the Coridene contained water, cod liver oil, hydrochloric acid, acetic acid, glutamic acid, copper sulfate, thymol, and eucalyptol.

The article was alleged to be misbranded in that certain statements in a booklet entitled "Gland-O-Lac Manual of Chicken Diseases" and in a circular entitled "This year . . . try Gland-O-Lac's Formula for Better Chicks," accompanying the article, were false and misleading since they represented and suggested that the article contained mold-inhibiting properties, antiseptic oils, and other ingredients beneficial to the chicks; that it would be efficacious in the cure, mitigation, treatment, and prevention of white diarrhea (pullorum disease), mycosis, erosions of the gizzard lining, nonspecific infections, coccidiosis of both the cecal type and intestinal type, and fowl typhoid; that it would be efficacious in the prevention of loss of blood, anemia, susceptibility to disease and bacterial infections; that it would aid in the production of red blood coloring matter; that it would supply important acids, antiseptic oils, and other ingredients essential to survival in the danger period; that it would protect the chicks from both internal and external parasites during the first week or two; that it would aid digestion and help avoid constipation, thereby assisting the intestines in throwing off infectious organisms; that it would clean out the blind intestine and prevent absorption of toxins from decomposed tissue trapped in the blind intestine; that its use would pay big dividends in poultry raising; that it would aid in the pro-

duction of better chicks and give chicks a better start and better livability; that its use would mean the difference between success and failure in the raising of chicks; that it would be efficacious to prevent the picking up of filth infection; and that it would prevent impaction and paralysis of the gizzard. The article did not contain mold-inhibiting properties, antiseptic oils, and other ingredients beneficial to chicks, and it would not be efficacious for the purposes claimed.

Analysis of the Neol disclosed that it contained mineral oil, eucalyptus, thyme, menthol, creosote, and chlorophyll. It was alleged to be misbranded in that certain statements in an accompanying booklet entitled "Gland-O-Lac Manual of Chicken Diseases" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of white diarrhea (pullorum disease), respiratory diseases, common colds, contagious coryza, bronchitis, brooder pneumonia, nutritional roup, laryngotracheitis, bacterial bronchitis, and roup; and that it would be efficacious in the control of worms and coccidiosis. The article would not be efficacious for the purposes claimed.

On March 16, 1945, a plea of *nolo contendere* having been entered on behalf of the defendant, the court imposed a fine of \$100 on count 1 relating to the Coridene and \$50 on count 2 relating to the Neol, a total fine of \$150 plus costs.

1447. Misbranding of Master Floresine. U. S. v. 22 Bottles of Master Floresine. Default decree of condemnation. Product destroyed. (F. D. C. No. 13330. Sample No. S7320-F.)

On August 23, 1944, the United States attorney for the District of South Dakota filed a libel against 22 pint bottles of Master Floresine, at Salem, S. Dak., alleging that the article had been shipped on or about April 19, 1944, by the Master Laboratories, from Omaha, Nebr.

Examination of a sample disclosed that the article consisted essentially of sulfonated castor oil with small amounts of water, guaiacol, cresol, camphor, oil of eucalyptus, and oil of tar.

The article was labeled in part: (Container label) "when taken internally it exerts an expectorant effect throughout the respiratory tract * * * In some cases when they are too sick to move about to drink or feed, then individual dosing will have to be given with a dose syringe. * * * There are certain ingredients in Master Floresine, which are highly beneficial when inhaled by the animals. * * * Although this medication product was designed for use in treating swine, it is of equal value in respiratory diseases of various other animals and birds. It is an efficient * * * antiferment and febrifuge. A direct local action is obtained when the animals inhale the vapors."

The article was alleged to be misbranded in that the statements on its label were false and misleading since the article, when used as directed, would not be effective in the prevention or treatment of any disease condition affecting the respiratory tract of animals; and, when taken internally, it would not exert an expectorant effect throughout the respiratory tract of animals.

On October 2, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be disposed of by the marshal. The product was destroyed.

1448. Misbranding of Dyatrol and Alkamix. U. S. v. 18 Packages of Dyatrol and 33 Packages of Alkamix. Default decree of condemnation and destruction. (F. D. C. No. 13307. Sample Nos. 54230-F, 54231-F, 54259-F, 54260-F.)

On August 23, 1944, the United States attorney for the District of Arizona filed a libel against 9 7-ounce packages and 9 15-ounce packages of Dyatrol, 22 2-pound packages and 11 6-pound packages of Alkamix, and a quantity of circulars entitled "On the March with Cooke's Tested Poultry Formulae . . . and in step for Better Poultry," and leaflets entitled "Cooke's Tested Poultry Formulae Alkamix The Whys and Wherefores," at Glendale, Ariz., alleging that the articles and the printed matter had been shipped on or about January 20, 1944, by Cooke Laboratory Products, Sepulveda, Calif.

Analysis disclosed that the Dyatrol consisted of coal-tar dyes, including methylene blue and methyl violet; ammonium chloride; phenolic substances; 53 percent of an acid-insoluble mineral, such as talc; and aromatics. Bacteriological examination showed that it failed to kill typhoid- and pus-producing organisms in 19 hours, when diluted as directed in the labeling. It was alleged to be misbranded because of false and misleading statements in the accompanying circulars and leaflets which represented and suggested that the article was an antiseptic; and

that it would be efficacious in preventing the spread of disease and in treating common colds, coughs, "wheezing," and minor bronchial irritations. The article was not an antiseptic, and it would not be an effective preventive or treatment of any disease condition affecting poultry.

Analysis of the Alkamix disclosed that it contained sodium phosphate, 40 percent; sodium thiosulfate, 15 percent; Epsom salt, 10 percent; dextrin, 8 percent; and smaller proportions of other compounds, including iron sulfate, an iodide, and a phenolic compound such as sodium orthophenylphenate. Bacteriological examination showed that the article diluted as recommended in the labeling failed to kill typhoid organisms in 6 hours or pus-producing organisms in 24 hours. It was alleged to be misbranded in that certain statements in the accompanying circulars and leaflets were false and misleading since they represented and suggested that the article would be efficacious in the prevention or treatment of various toxemias, colds, coryza, sinusitis, diarrhea, intestinal parasites, coccidiosis, enteritis, blackhead, and acidosis; that it would increase the water and feed consumed by poultry; that it was an antiseptic; that it was of value in checking the development of harmful bacterial and fungus growths in the drinking water and crop; that it would aid in maintaining the acid-alkaline balance of the body fluids; and that it would stimulate metabolism or normal body functions. The article would not be efficacious for such purposes or for any disease condition of poultry.

On October 3, 1944, no claimant having appeared, judgment of condemnation was entered and the products, including the circulars and leaflets, were ordered destroyed.

1449. Misbranding of Robertson's Worm Expeller. U. S. v. 144 Packages of Robertson's Worm Expeller. Default decree of condemnation and destruction. (F. D. C. No. 13076. Sample No. 80113-F.)

On July 27, 1944, the United States attorney for the Eastern District of Illinois filed a libel against 144 1-pound packages of the above-named product at East St. Louis, Ill., alleging that the article had been shipped on or about April 26, 1944, by the F. B. Chamberlain Co., from St. Louis, Mo.

The article was alleged to be misbranded in that the name on the label, "Worm Expeller For Hogs," was false and misleading since examination showed that the article contained 61 percent of inorganic material, including compounds of iron, magnesium, and sodium, with plant material derived from areca nut, and a small proportion of American wormseed; and an article of this composition would have no value as an expeller for any species of worms that infest hogs.

On August 22, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1450. Misbranding of Dry Protosep. U. S. v. 1 Barrel of Dry Protosep. Default decree of condemnation and destruction. (F. D. C. No. 12883. Sample No. 58699-F.)

On July 6, 1944, the United States attorney for the Eastern District of Virginia filed a libel against 1 barrel containing 250 pounds of Dry Protosep at Richmond, Va., alleging that the article had been shipped on or about May 31, 1944, from Myerstown, Pa., by the Whitmoyer Laboratories, Inc. The article was labeled as containing the following: "Ingredients Active:—Hydrochloric Acid, Benzoic Acid, Lactic Acid, Thymol, Oil of Eucalyptus, Fortified Cod Liver Oil, Copper Gluconate, Calcium Gluconate. Inert:—Bentonite, Vegetable Pulp, Water."

The article was alleged to be misbranded in that the following labeling statements were false and misleading: (Barrel label) "A scientific flock treatment for growing stock and layers * * * for Prevention—When the chicks become 2 weeks of age, proceed as follows: Administer dry PROTOSEP one day each week, using four pounds (4%) of dry PROTOSEP and 3 lbs. (3%) Epsom Salts to every 100 pounds of regular mash (or use the special formula shown under 'Treatment') one day each week. Continue to feed this PROTOSEP treated mash one day each week until the chicks become 10 or 12 weeks of age"; (pink tag label accompanying the article) "* * * DRY PROTOSEP For the Control and Treatment of Coccidiosis * * * For Prevention—* * * administer DRY PROTOSEP mash one day each week. * * * —For Treatment—* * * Start feeding PROTOSEP treated mash for the balance of the day and for the next 3 days. Take away all grain until the treatment is completed. At the conclusion of the 4-day treatment start the regular feeding

program again." The article, when used as directed, would not be effective as a flock treatment or preventive of any disease condition of poultry; and it would have no value in the prevention, treatment, or control of coccidiosis of poultry.

On July 29, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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¹ Permanent injunction issued. Contains findings of fact, conclusions of law, and other for judgment.

² Permanent injunction issued.

³ Injunction issued.

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Aditis-----	1405	rectal suppositories-----	1442
Killashun Sales Division:		Wyeth, John, & Brother, Inc.:	
prophylactics-----	1435	dextrose ampuls and sodium io-	
		dide ampuls-----	1421

¹ Permanent injunction issued. Contains findings of fact, conclusions of law, and order for judgment.

² Injunction issued.

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Official Daily Service



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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1451-1500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., January 24, 1946.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1451. Misbranding of Bristol's Compound and Kemp's Vermifuge (liquid). U. S. v. 153 Dozen Packages of Bristol's Compound and 289 Dozen Packages of Kemp's Vermifuge (liquid). Default decree of forfeiture and destruction. (F. D. C. No. 14428. Sample Nos. 33165-F, 33169-F.)

On November 14, 1944, the United States attorney for the District of Puerto Rico filed a libel against 153 dozen packages of Bristol's Compound and 289 dozen packages of Kemp's Vermifuge (liquid) at San Juan, P. R., alleging that the articles had been shipped between the approximate dates of March 14 and October 23, 1944, from New York, N. Y., by Lanman and Kemp-Barclay and Co., Inc.

Examination of the Bristol's Compound showed that it contained extracts of plant drugs, including a laxative plant drug such as senna, and an iodide such as potassium iodide. It was alleged to be misbranded in that its labeling failed to warn that the article should not be used in cases of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the article or use in accordance with the directions, namely, "For adults, one tablespoonful * * * three times daily * * * For children 3 to 5 years old, ½ teaspoonful; 6 to 11 years, 1 teaspoonful; 12 to 15 years, 2 teaspoonfuls; 16 to 18 years, 3 teaspoonfuls * * * three times daily," might result in dependence upon laxatives to move the bowels. It was alleged to be misbranded

* For drugs actionable because of failure to bear adequate directions or warning statements, see No. 1451; omission of, or unsatisfactory, ingredients statements, Nos. 1470, 1485, 1494; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1481; failure to bear an accurate statement of the quantity of the contents, No. 1492; cosmetics, subject to the drug provisions of the Act, Nos. 1491, 1492.

further in that the statement on its labels, "indicated in the treatment of skin eruptions resulting from faulty elimination," was misleading since a purchaser had no way of knowing whether skin eruptions were due to faulty elimination or to some other condition.

The Kemp's Vermifuge (liquid) was labeled in part: "Formula per 100 c. c.—Active Ingredients: Oil chenopodium 3.40 c. c., castor oil 82.80 c. c., and the matter extracted from: pomagranate bark 2.80 gms., spigelia root 1.80 gms., senna leaves 1.10 gms. * * * Dose: Children 1 to 2 years, 30 Drops (1.20 cc.) Children 2 to 5 years, 1 Teaspoonful 4 c. c. Children 5 to 8 years, 2 Teaspoonfuls 8 c. c. Children 8 to 12 years, 3 Teaspoonfuls 12 c. c. Adults 1 Tablespoonful 15 c. c. Instructions: Take at night on retiring. If desired result is not produced by morning, the dose may be repeated." Examination of the article indicated that it possessed essentially the composition stated upon its label. It was alleged to be misbranded in that, by reason of its content of Chenopodium oil, it was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling. It was alleged to be misbranded further in that the following statements appearing in the circular entitled "Kemp's Vermifuge" were misleading: "Usual Symptoms of The Presence of Intestinal Worms. The patient loses color and weight and his abdomen becomes swollen and hard, he complains of pains in the stomach and in the region of the navel; his appetite is capricious and he craves sweets; he scratches his nose almost continuously or grinds his teeth in his sleep." The conditions mentioned above might have been due to various causes other than the presence of intestinal worms, and they might have led to the use of the article in conditions for which it would be of no value.

On April 17, 1945, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1452. Misbranding of Nion D Capsules. U. S. v. 6 Cases of Nion D Capsules. Default decree of condemnation and destruction. (F. D. C. No. 14424. Sample No. 73943-F.)

On November 15, 1944, the United States attorney for the District of Arizona filed a libel against 6 cases, each containing 6 cartons of 100 capsules each, of Nion D Capsules at Phoenix, Ariz., alleging that the article had been shipped on or about August 4, 1944, by the Nion Corporation, Los Angeles, Calif. The article was represented on its label as containing 50,000 U. S. P. units of vitamin D per capsule.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested by its labeling, "One capsule four times a day for the first month, increasing a capsule a day per week up to ten capsules per day."

On March 20, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1453. Misbranding of Boyle Vitamin D Capsules. U. S. v. 13 Bottles of Boyle Vitamin D Capsules. Default decree of condemnation and destruction. (F. D. C. No. 14013. Sample No. 74290-F.)

On October 11, 1944, the United States attorney for the District of Arizona filed a libel against 13 100-capsule bottles of the above-mentioned product at Phoenix, Ariz., alleging that the article had been shipped on or about July 8, 1944, by Boyle and Co., Los Angeles, Calif.

Examination showed that the article contained approximately 50,000 U. S. P. units of vitamin D per capsule.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested by the labeling, namely, "One capsule 4 times a day for first month, increasing a capsule a day per week up to 10 capsules per day."

On November 21, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DECOMPOSITION OR CONTAMINATION WITH FILTH

1454. Adulteration and misbranding of Mela-Vim. U. S. v. 650 Bottles of Mela-Vim. Default decree of condemnation and destruction. (F. D. C. No. 14369. Sample No. 63930-F.)

On November 16, 1944, the United States attorney for the Southern District of Florida filed a libel against 650 bottles of Mela-Vim at Jacksonville, Fla., alleging

that the article had been shipped on or about September 12, 1944, from Newburgh, N. Y., by Louis Sampanis.

Examination showed that the article consisted essentially of water with extracts of plant materials and traces of iron and ammonium compounds, and that it was contaminated with mold.

The article was alleged to be adulterated in that it consisted in whole or in part of a decomposed substance. It was alleged to be misbranded in that certain statements on the bottle labels and on the labels and circulars which were shipped with the article were false and misleading since they represented and suggested that the article would be effective in the treatment of anemia, diabetes, eruptions of the skin, high or low blood pressure, fistula of the arteries, varicose veins, eczema, pimples, ulcers of the stomach, hemorrhoids, rheumatism, neurasthenia, unhealthy blood, menstrual disorders, underdeveloped, high-strung, or weak children, poor circulation, chronic venereal diseases, syphilis, and gonorrhea. The article contained no ingredients or combination of ingredients which would be effective in the treatment of the disease conditions mentioned.

On November 29, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1455. Adulteration of mouse ear herb. U. S. v. 1 Metal Container of Mouse Ear Herb. Default decree of condemnation and destruction. (F. D. C. No. 13668. Sample No. 86550-F.)

On September 20, 1944, the United States attorney for the Northern District of Indiana filed a libel against 1 metal container containing about 24 pounds of mouse ear herb at Hammond, Ind., alleging that the article had been shipped on or about August 8, 1944, by J. L. Hopkins & Co., New York, N. Y.

The article was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence of rodent hair fragments and insect fragments.

On November 13, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1456. Adulteration of rhubarb root. U. S. v. 1 Barrel of Rhubarb Root. Default decree of condemnation and destruction. (F. D. C. No. 13713. Sample No. 90391-F.)

On September 20, 1944, the United States attorney for the Eastern District of Missouri filed a libel against 1 barrel of rhubarb root at St. Louis, Mo., alleging that the article had been shipped on or about August 4, 1944, by J. L. Hopkins & Co., from New York, N. Y.

The article was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence of insect fragments and rodent hair fragments.

On November 27, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1457. Adulteration of corn silk. U. S. v. 1,418 Pounds of Corn Silk. Default decree of condemnation and destruction. (F. D. C. No. 13818. Sample No. 85025-F.)

On September 23, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 1,418 pounds of corn silk at Philadelphia, Pa., alleging that the article had been shipped on or about August 17, 1944, from New York, N. Y., by J. L. Hopkins and Co.

The article was alleged to be adulterated in that it consisted in whole or in part of a filthy substance by reason of the presence of whole insects, beetle eggs, insect fragments, mites, thrips, and insect excreta pellets.

On November 22, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1458. Adulteration and misbranding of Broncotol and tincture of nux vomica. U. S. v. Standard Pharmaceutical Corporation. Plea of guilty. Fine, \$1,000 and costs. (F. D. C. No. 14296. Sample Nos. 35938-F, 35941-F.)

On February 23, 1945, the United States attorney for the District of Maryland filed an information against the Standard Pharmaceutical Corporation, Baltimore, Md., alleging shipment of quantities of Broncotol and tincture of nux vomica from the State of Maryland into the State of Georgia on or about January 14 and February 3, 1944.

The Broncotol was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented on its label as containing $\frac{1}{2}$ grain of codeine phosphate per fluid ounce, whereas it contained 0.651 grain of codeine phosphate per fluid ounce. It was alleged to be misbranded in that the label statement, "Each fluid ounce contains Codeine Phosphate $\frac{1}{2}$ grain," was false and misleading.

The tincture of nux vomica was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since the Pharmacopoeia provides that "Tincture of Nux Vomica yields from each 100 cc., * * * not more than 0.125 Gm. of strychnine," whereas the article yielded from each 100 cc. not less than 0.135 gram of strychnine; and its difference in strength from the standard was not plainly stated, or stated at all, on its label. The article was alleged to be misbranded in that the label statement, "Tincture Nux Vomica * * * U. S. P. * * * Each 100 cc. contains not * * * more than 0.125 Gm. of Strychnine," was false and misleading.

On March 16, 1945, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$250 on each of 4 counts of the information, a total fine of \$1,000, plus costs.

1459. Adulteration and misbranding of thiamine chloride tablets. U. S. v. William S. McClymonds (Western Research Laboratories). Plea of nolo contendere. Fine, \$50. (F. D. C. No. 14231. Sample Nos. 6555-F, 36500-F.)

On January 22, 1945, the United States attorney for the District of Colorado filed an information against William S. McClymonds, trading as the Western Research Laboratories, Denver, Colo., alleging shipment of a quantity of thiamine chloride tablets on or about August 28 and November 20, 1943, from the State of Colorado into the States of Wyoming and Utah.

The article was alleged to be adulterated in that it purported to be and was represented as "Thiamine-Chloride Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the official standard since the Pharmacopoeia requires that thiamine chloride tablets shall contain not less than 95 percent of the labeled amount of thiamine chloride, whereas the article contained, in the case of one lot, not more than 60 percent and, in the case of the remaining lot, not more than 73 percent of the labeled amount of thiamine chloride. The article was alleged to be misbranded in that the statements on its labels, "Tablets Thiamin Chloride 5 mgm. [or "10 mgm.]," were false and misleading since the article contained smaller amounts of thiamine chloride than was represented."

The information also alleged that two other products, pyridamide tablets and thiamine chloride solution, were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 8086.

On February 3, 1945, the defendant having entered a plea of nolo contendere, the court imposed a fine of \$5 on each of the 10 counts of the information.

1460. Adulteration and misbranding of Brewer Vitamin Concentrate Capsules. U. S. v. 97 Boxes and 104 Boxes of Vitamin Capsules. Decree of condemnation and destruction. (F. D. C. No. 6092. Sample No. 75735-E.)

On October 27, 1941, the United States attorney for the District of Maine filed a libel against 97 boxes, each containing 100 capsules, and 104 boxes, each containing 50 capsules, of vitamins at Waterville, Maine, alleging that the article had been shipped on or about April 16, 1941, by Brewer & Co., Inc., from Worcester, Mass. The article was labeled in part: "Brewer Vitamin Concentrate Capsules Containing Vitamins A-B-D-G."

A vitamin assay of a sample showed that the article contained not more than 700 U. S. P. units of vitamin D per capsule.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess: "Vitamin D 1,000 units U. S. P. XI."

The article was alleged to be misbranded (1) in that the statement on its label, "Vitamin D 1,000 units U. S. P. XI," was false; and (2) in that the conspicuous declaration on the main display panel, "Containing vitamins * * * G," was misleading in view of the fact that the article, when taken according to the directions, "Average daily Dose 1 to 3 capsules," would furnish not more than 8 percent of the minimum daily requirement for vitamin G.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 8098.

On February 2, 1945, the sole intervener having withdrawn its claim and answer, judgment of condemnation was entered and the product was ordered destroyed.

1461. Adulteration of vitamin B complex. U. S. v. 43 Vials of Vitamin B Complex. Default decree of condemnation and destruction. (F. D. C. No. 14048. Sample No. 79818-F.)

On October 18, 1944, the United States attorney for the District of Maryland filed a libel against 43 vials, each containing 10 cubic centimeters, of the above-named product at Baltimore, Md., alleging that the article had been shipped on or about September 9, 1944, from Philadelphia, Pa., by the Associated Laboratories, Inc.

This article was packaged in vials enclosed with a rubber cap such as is in common use in products intended for parenteral administration.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, i. e., for parenteral administration, since it was contaminated with undissolved material.

On November 25, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1462. Adulteration and misbranding of Spear 15% "All Mash" Egg Mash. U. S. v. 9 Sacks of Spear 15% "All Mash" Egg Mash. Decree of condemnation and destruction. (F. D. C. No. 14003. Sample No. 66869-F.)

On or about October 20, 1944, the United States attorney for the District of Kansas filed a libel against 9 100-pound sacks of the above-mentioned product at Kansas City, Kans., alleging that the article had been shipped on or about August 29, 1944, by the Spear Mills, Inc., from Kansas City, Mo.

Analysis indicated that the article contained little or no phenothiazine, and that it contained 115 grains of nicotine sulfate per 100 pounds.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess since it was labeled as containing "not less than 385 grains of Phenothiazine per 100 lbs.," whereas it contained little or no phenothiazine.

The article was alleged to be misbranded because of false and misleading statements in its labeling regarding its efficacy in the removal of all species of worms that infest poultry. It was alleged to be misbranded further in that the label statements, "preparation for Large Round Worms (*Ascaridia Lineate*) Control composed of these active ingredients: * * * Phenothiazine, Nicotine Sulphate," and "Contains 115 grains Nicotine Sulphate as Alkaloid from tobacco per 100 pounds," were false and misleading since the amount of nicotine sulfate contained in the article would not be effective as an anthelmintic (worm remover), and since the product contained little or no phenothiazine.

On October 20, 1944, the owner having admitted that the product was adulterated and misbranded, judgment of condemnation was entered and the article was ordered destroyed.

1463. Adulteration of vitamin C and aminophylline. U. S. v. 2 Boxes of Vitamin C and 10 Boxes of Aminophylline. Default decree of condemnation and destruction. (F. D. C. No. 13793. Sample Nos. 84910-F to 84912-F, incl.)

On September 14, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2 boxes containing a total of 175 ampuls, 5-cc. size, of vitamin C and against 2 boxes containing a total of 175 ampuls, 10-cc. size, and 8 boxes containing a total of 175 ampuls, 20-cc. size, of aminophylline at Philadelphia, Pa., alleging that the article had been shipped on or about August 7, 1944, from New York, N. Y., by the Metropolitan Laboratories, Inc.

The aminophylline was alleged to be adulterated in that it purported to be and was represented as theophylline ethylenediamine injection (aminophylline ampuls), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the article was not free of undissolved material.

The vitamin C was alleged to be adulterated in that its quality and purity fell below that which it purported and was represented to possess, since it was labeled "For Intravenous Injection," indicating that it had the quality and purity appropriate for such use, whereas its quality and purity was not appropriate for that purpose by reason of the presence of undissolved material in the solution.

On October 10, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1464. Adulteration of aminophylline. U. S. v. 172 Ampuls of Aminophylline. Decree of condemnation and destruction. (F. D. C. No. 14443. Sample No. 85208-F.)

On November 20, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 172 ampuls, 20 cc. size, of aminophylline at Philadelphia, Pa., alleging that the article had been shipped on or about September 29, 1944, from New York, N. Y., by the Estro Chemical Co.

The article was alleged to be adulterated in that it purported to be and was represented as theophylline ethylenediamine injection (aminophylline ampuls), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since the article was not free of undissolved material.

On February 20, 1945, the Estro Chemical Co., claimant, filed an answer which alleged that the product, when manufactured, was in full accordance with the then existing United States Pharmacopoeia and was free of undissolved material at the time of shipment. However, the answer failed to deny the allegations of the libel that the product, at the time of seizure, contained undissolved material and therefore was adulterated. A motion for judgment was filed by the Government's attorney, based on the insufficiency of the claimant's answer, and the court, after consideration of the matter, entered judgment in favor of the Government. On the same date, a decree of condemnation was entered against the product, and it was ordered destroyed.

1465. Adulteration of isotonic sodium chloride solution, isotonic solution of three chlorides, and lactate Ringer's solution. U. S. v. 138 Bottles of Isotonic Sodium Chloride Solution (and 2 other seizure actions against drugs intended for parenteral use). Default decrees of condemnation and destruction. (F. D. C. Nos. 14323 to 14325, incl. Sample Nos. 82734-F, 82739-F, 82745-F, 82747-F to 82753-F, incl.)

On October 30 and November 3, 1944, the United States attorney for the Southern District of New York filed libels against 138 bottles of isotonic sodium chloride solution, 77 bottles of isotonic solution of three chlorides, and 45 bottles of lactate Ringer's solution, at New York, N. Y., alleging that the articles had been shipped during the year 1944, from Chicago, Ill., by Hospital Liquids, Inc.

The isotonic sodium chloride solution and the isotonic solution of three chlorides were alleged to be adulterated in that they purported to be "Sterile Isotonic Solution of Sodium Chloride for Parenteral Use" and "Sterile Isotonic Solution of Three Chlorides for Parenteral Use," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the standards set forth therein since the articles were contaminated with undissolved material.

The lactate Ringer's solution was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, since it purported to be and was represented as suitable for parenteral use, whereas it was not suitable for such use since it contained undissolved material.

Between November 17 and December 7, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1466. Adulteration of sodium citrate solution. U. S. v. 702 Ampuls of Sodium Citrate Solution. Default decree of condemnation and destruction. (F. D. C. No. 13800. Sample No. 82802-F.)

On September 21, 1944, the United States attorney for the District of New Jersey filed a libel against 702 ampuls of the above-named product at Jersey City, N. J.; and on September 25, 1944, an amended libel was filed to include the seizure of an additional lot of 88 ampuls of the product at the same place. It was alleged in the amended libel that the article had been shipped on or about January 29 and March 6, 1944, from New York, N. Y., by the Loesser Laboratory, Inc. The article was labeled in part: "Sterile Solution Sodium Citrate 2½% (W/V) For Use in Blood Transfusion."

The article was alleged to be adulterated in that it purported to be and was represented as "Sterile Anticoagulant Solution of Sodium Citrate for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the article was contaminated with undissolved material.

On November 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1467. Adulteration of ampuls sodium salicylate. U. S. v. 575 Ampuls of Sodium Salicylate. Default decree of condemnation and destruction. (F. D. C. No. 14207. Sample No. 90342-F.)

On November 7, 1944, the United States attorney for the Eastern District of Arkansas filed a libel against 575 ampuls of sodium salicylate at Little Rock, Ark., alleging that the article had been shipped on or about September 21, 1944, from Brooklyn, N. Y., by the Adson-Intrasol Laboratories, Inc.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since the article was contaminated with undissolved material.

On December 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1468. Adulteration of boric acid. U. S. v. 13 Dozen Cartons of Boric Acid. Default decree of condemnation and destruction. (F. D. C. No. 14106. Sample Nos. 69509-F, 69518-F.)

On October 23, 1944, the United States attorney for the District of New Mexico filed a libel against 13 dozen cartons of boric acid at Santa Fe, N. Mex., alleging that the article had been shipped on or about May 11, 1943, and March 1, 1944, from Oklahoma City, Okla., by the Scotch-Tone Co.

The article was alleged to be adulterated in that alum had been substituted in whole or in part for boric acid, which the article was represented to be.

On December 1, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1469. Adulteration of iron cacodylate. U. S. v. 950 Ampuls of Iron Cacodylate. Default decree of condemnation and destruction. (F. D. C. No. 14041. Sample No. 64075-F.)

On October 16, 1944, the United States attorney for the Northern District of Georgia filed a libel against 950 ampuls, each containing 5 cc., of iron cacodylate at Atlanta, Ga., alleging that the article had been shipped on or about September 8, 1944, by the Adson-Intrasol Laboratories, Inc., from Brooklyn, N. Y. The article was labeled in part: "Iron cacodylate * * * intravenously."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported and was represented to possess, since it was contaminated with undissolved material.

On December 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1470. Adulteration and misbranding of Digifortis. U. S. v. 1,156 Bottles of Digitalis. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14085. Sample No. 78785-F.)

On November 2, 1944, the United States attorney for the Northern District of Illinois filed a libel against 1,156 bottles of Digifortis at Chicago, Ill., alleging that the article had been shipped on or about August 21, 1944, from Detroit, Mich., by Parke, Davis & Co. The article was labeled in part: "Digifortis * * * 125% Strength of Tincture Digitalis of International Standard."

The United States Pharmacopoeia specifies that 1 cc. of tincture of digitalis shall be equivalent to 1.0 U. S. P. digitalis unit; and it provides that tincture of digitalis which varies not more than 20 percent from the Pharmacopoeial requirement shall be considered to conform to that requirement. Examination of a sample of the article by the method prescribed in the Pharmacopoeia for tincture of digitalis showed that its potency was not less than 2.1 U. S. P. digitalis units per cubic centimeter.

The article was alleged to be adulterated in that it purported to be tincture of digitalis, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth in that compendium, and its difference in strength from the standard was not plainly stated on its label.

The article was alleged to be misbranded in that it was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug, i. e., tincture of digitalis. The article was alleged to be misbranded further (1) in that the statements in its labeling, (carton and bottle labels) "Original potency continued by the use of the International Standard and the lethal dose frog method of assay," and (circular

entitled "Digifortis Products") "The various Digifortis products provide the medical practitioner with Digitalis preparations of * * * uniform quality. They include Liquid Digifortis," were false and misleading since such statements created the impression that standardization of the article by use of a lethal dose frog method of assay enabled the maintenance of a definite clinical potency for humans, whereas standardization of the article by that method would not enable the maintenance of a definite clinical potency for humans; and (2) the statement on the label and carton of the article, "125% Strength of Tincture Digitalis of International Standard," was false and misleading since it created the impression that the potency of the article was 125 percent of that of tincture of digitalis as described in the United States Pharmacopoeia, which recognizes as a synonym for tincture of digitalis "Tinctura Digitalis P. I. [Protocol Internationale]," whereas the actual strength of the article was more than 200 percent of tincture of digitalis as described in the Pharmacopoeia.

On February 20, 1945, Parke, Davis and Co., claimant, having admitted the facts in the libel, judgment of condemnation was entered and the product was ordered released under bond for remanufacturing and relabeling under the supervision of the Food and Drug Administration.

1471. Adulteration of Narcosan, Narcosan-A, Elevin, Osmogen, and Sinesin. U. S. v. 6 Boxes of Narcosan, 11 Boxes of Narcosan-A, 2 Boxes of Elevin, 3 Boxes of Osmogen and 3 Boxes of Sinesin. Default decree of condemnation and destruction. (F. D. C. No. 13428. Sample Nos. 53766-F, 53769-F, 53771-F, 53773-F, 53776-F, 53777-F.)

On August 25, 1944, the United States attorney for the Southern District of California filed a libel against 6 boxes of Narcosan, 11 boxes of Narcosan-A, 2 boxes of Elevin, 3 boxes of Osmogen, and 2 boxes of Sinesin, each box containing 12 ampuls (1-cc. size), and against 1 box containing 30 cc. of Sinesin, at Los Angeles, Calif., alleging that the articles had been shipped by the Lipoidal Laboratories, from New York, N. Y. It was also alleged that shipments of the Narcosan and Narcosan-A were made on or about June 28 and October 15, 1943, respectively, and that the shipment dates of the other articles were unknown.

Examination showed that the articles, each of which bore directions for intramuscular administration, were contaminated with living micro-organisms and therefore unsuitable for intramuscular administration.

The articles were alleged to be adulterated in that their purity and quality fell below that which they purported and were represented to possess.

On September 19, 1944, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1472. Adulteration of triple distilled water. U. S. v. 270 Ampuls and 1,990 Ampuls of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 14010. Sample No. 64073-F.)

On or about October 12, 1944, the United States attorney for the Northern District of Georgia filed a libel against 270 5-cc. ampuls and 1,990 10-cc. ampuls of triple distilled water at Atlanta, Ga., alleging that the article had been shipped on or about August 10, 1944, by the American Medical Specialties Co., Inc., from New York, N. Y.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the compendium provides that water for injection is a clear liquid, whereas the article was not a clear liquid but contained suspended material.

On March 16, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1473. Adulteration of triple distilled water. U. S. v. 350 Ampuls of Triple Distilled Water. Default decree of condemnation. Product ordered delivered to the Food and Drug Administration. (F. D. C. No. 13819. Sample No. 78856-F.)

On September 26, 1944, the United States attorney for the Eastern District of Michigan filed a libel against 350 ampuls, 10-cc. size, of the above-named product at Detroit, Mich., alleging that the article had been shipped on or about July 15, 1944, by the Torigan Laboratories, Inc., Queens Village, N. Y. The article was labeled in part: "Triple Distilled Water for Injection."

Examination showed that the article contained pyrogens and was contaminated with undissolved material.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it failed to meet the pyrogen test prescribed in the Pharmacopoeia, and it contained undissolved material.

On December 8, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration, for technical use.

1474. Adulteration of adhesive plaster. U. S. v. 852 Spools and 35,100 Rolls of Adhesive Plaster. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 14012, 14429. Sample Nos. 52976-F, 92906-F.)

On or about October 5 and November 14, 1944, the United States attorney for the District of Maryland filed libels against 852 spools and 35,100 rolls of adhesive plaster at Baltimore, Md., alleging that the article had been shipped on or about April 18, 1944, by the Richmond Army Service Forces Depot, from Bellbluff, Va. The article was labeled in part: "Gotham Adhesive Plaster * * * Manufactured by Gotham Aseptic Laboratory Co. Inc. New York, N. Y."

The article was alleged to be adulterated in that it purported to be and was represented as adhesive plaster, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since the compendium provides that the adhesive strength of adhesive plaster, when determined by the method specified therein, shall be not less than 40 pounds, whereas the adhesive strength of the product in spools was from 3 to 19 pounds and that in rolls was from 3 to 11 pounds.

On November 14, 1944, no claimant having appeared for the spools of the product, judgment of condemnation was entered and that portion was ordered destroyed. On January 17, 1945, B. Pierce and Co., Inc., Baltimore, Md., having appeared as claimant for the remainder of the product and having admitted that the article was adulterated, judgment of condemnation was entered and the article was ordered released under bond to be disposed of in compliance with the law. It was not to be used as surgical adhesive plaster.

1475. Adulteration of adhesive plaster. U. S. v. 16½ Cartons of Adhesive Plaster. Default decree of condemnation and destruction. (F. D. C. No. 14394. Sample No. 2523-F.)

On November 9, 1944, the United States attorney for the Eastern District of Oklahoma filed a libel against 16½ cartons, each full carton containing 144 packages, of adhesive plaster at Wewoka, Okla., alleging that the article had been shipped on or about April 28 and July 24, 1944, by the Maryland Salvage Co., from Baltimore, Md. The article was labeled in part: "Gotham Adhesive Plaster * * * Manufactured By Gotham Aseptic Laboratory Co. Inc. New York, N. Y."

The article was alleged to be adulterated in that it purported to be and was represented as adhesive plaster, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard, which provides that the adhesive strength of adhesive plaster, when determined by the method specified therein, shall be not less than 40 pounds, whereas the adhesive strength of the article was from 3 to 19 pounds.

On January 16, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1476. Adulteration of Sanette Treated Strips. U. S. v. 49½ Gross Packages of Sanette Treated Strips. Default decree of condemnation and destruction. (F. D. C. No. 14469. Sample No. 75658-F.)

On November 11, 1944, the United States attorney for the Western District of Pennsylvania filed a libel against 49½ gross packages of Sanette Treated Strips at Pittsburgh, Pa., alleging that the article had been shipped on or about September 29, 1944, from Youkers, N. Y., by C. I. Lee and Co., Inc. The article was labeled in part: "Sanette 8 Treated Strips Sanette Mfg. Co. New York, N. Y."

Each package of the article contained a number of individual dressings prepared by affixing an absorbent compress, composed of several layers of absorbent gauze, to a strip of adhesive plaster.

The article was alleged to be adulterated in that it purported to be adhesive absorbent gauze, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

On December 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1477. Adulteration and misbranding of gauze bandages. U. S. v. 24½ Gross Packages of Gauze Bandages. Default decree of condemnation. Product ordered sold. (F. D. C. No. 14433. Sample No. 63634-F.)

On November 20, 1944, the United States attorney for the Northern District of Georgia filed a libel against 24½ gross packages of gauze bandages at Atlanta, Ga., alleging that the article had been shipped on or about October 3, 1944, by the Hampton Manufacturing Co., from Carlstadt, N. J. The article was labeled in part: "Blue Cross 2 Inches 6 Yds. Gauze Bandage."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile. It was alleged to be misbranded in that the label statement "Sterilized" was false and misleading.

On May 1, 1945, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be sold on condition that the packages would be stamped "Not sterilized and not to be used on open wounds or as a surgical dressing," and that the product would not be resold by the purchaser.

1478. Adulteration and misbranding of gauze bandage. U. S. v. 21 Cartons of Gauze Bandage. Default decree of condemnation and destruction. (F. D. C. No. 13365. Sample No. 81843-F.)

On or about August 21, 1944, the United States attorney for the District of Connecticut filed a libel against 21 cartons, each containing 12 packages, of gauze bandage at Bridgeport, Conn., alleging that the article had been shipped on or about June 29, 1944, from New York, N. Y., by the Supreme First Aid Co., Inc. The article was labeled in part: "1 inch 6 yards Supreme Gauze Bandage Sterilized."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile. The article was alleged to be misbranded in that the label statement "Sterilized" was false and misleading.

On October 27, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1479. Adulteration and misbranding of first aid kits. U. S. v. 97 Packages of First Aid Kits. Default decree of condemnation. Product ordered delivered to a public welfare organization. (F. D. C. No. 13366. Sample No. 58976-F.)

On August 18, 1944, the United States attorney for the District of Maryland filed a libel against 97 packages of first aid kits at Baltimore, Md., alleging that the article had been shipped on or about February 16 and May 22, 1944, from Avalon, Pittsburgh, Pa., by the Gus J. Schaffner Co. The article was labeled in part: "Schaffner's 'Little Doc' Jr. * * * First Aid Kit * * * Contains 2 ½ in. by 2-½ yds. Adhesive Tape."

Each kit contained, among other things, a carton labeled, "Schaffner's 'Little Doc' White Absorbent Cotton Sterilized After Packing," and only one roll of adhesive tape, the space intended for the other roll of adhesive tape having been filled with cardboard.

The article was alleged to be adulterated in that the absorbent cotton contained therein purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since the cotton was not sterile.

The article was alleged to be misbranded (1) in that the statements in its labeling, (large carton) "Contents as follows: * * * Sterilized Absorbent Cotton * * * Your First Line of Defense Against Infection," and (carton containing absorbent cotton) "Sterilized After Packing," were false and misleading as applied to an article containing unsterile cotton; and (2) in that the statement, "Contains * * * 2 ½ in. by 2-½ yds. Adhesive Tape," was false and misleading since the article did not contain 2 rolls of adhesive tape.

On September 26, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a public welfare organization.

1480. Adulteration and misbranding of prophylactics. U. S. v. 19 Gross of Prophylactics. Default decree of destruction. (F. D. C. No. 13899. Sample No. 80939-F.)

On or about October 9, 1944, the United States attorney for the Western District of Missouri filed a libel against 19 gross of prophylactics at Kansas City, Mo., alleging that the article had been shipped on or about August 30, 1944, by International Distributors, from Memphis, Tenn. The article was labeled in part: "Silver-Tex Prophylactics."

Samples of the article were found to be defective because of the presence of holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess.

It was alleged to be misbranded in that the labeling statements, "Prophylactics" and "for the prevention of disease," were false and misleading since the article contained holes.

On November 16, 1944, no claimant having appeared, judgment was entered ordering the product destroyed.

1481. Adulteration and misbranding of prophylactics. U. S. v. 38 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 13427. Sample No. 80284-F.)

On August 25, 1944, the United States attorney for the Eastern District of Missouri filed a libel against 38 gross of prophylactics at St. Louis, Mo., alleging that the article had been shipped on or about August 3, 1944, from Indianapolis, Ind., by Donald Beaumont. The article was labeled in part: "deluxe Silver Ray."

Examination of samples disclosed that the article was defective in that it contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded (1) in that the label statements, "Sold For Prevention of Diseases Only Triple Air Tested Guaranteed Five Years" and "deluxe Guaranteed 5 Years Disease Preventative," were false and misleading as applied to an article which contained holes; and (2) in that it was in package form and failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

On September 18, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS AND DEVICES FOR HUMAN USE

1482. Misbranding of Alliodis. U. S. v. 12 Cartons, 15 Cartons, and 1 Carton of Alliodis. Default decree of condemnation and destruction. (F. D. C. No. 14426. Sample No. 80951-F.)

On November 15, 1944, the United States attorney for the Western District of Oklahoma filed a libel against 12 cartons, each containing 50 capsules, 15 cartons, each containing 100 capsules, and 1 carton containing 1,000 capsules of Alliodis at Oklahoma City, Okla., alleging that the article had been shipped on or about August 23 and September 19, 1944, by the Neuhaus Products Co., from Los Angeles, Calif.

Examination showed that the article was an olive oil extract of mascerated garlic.

The article was alleged to be misbranded in that certain statements in an accompanying circular entitled "Alliodis in Functional Hypertension" were false and misleading since they represented and suggested that the article was effective for the reduction of high blood pressure (hypertension), whereas the article was not effective for that purpose.

On January 10, 1945, no claimant having appeared, judgment of condemnation was entered and the product, together with the circular, was ordered destroyed.

1483. Misbranding of Bennett's Pep-Em-Up. U. S. v. 45 Bottles of Bennett's Pep-Em-Up. Default decree of condemnation and destruction. (F. D. C. No. 12918. Sample No. 28878-F.)

On or about July 15, 1944, the United States attorney for the Southern District of Florida filed a libel against 45 bottles, each containing 6 fluid ounces, of the

*See also Nos. 1451, 1454, 1458-1460, 1462, 1470, 1477-1481.

above-named product at Jacksonville, Fla., alleging that the article had been shipped on or about March 24, 1944, from St. Louis, Mo., by the S. Pfeiffer Manufacturing Co.

Examination showed that the article was a brown liquid consisting essentially of water, alcohol (3.48 percent), and small amounts of plant extractives.

The article was alleged to be misbranded in that the name "Pep-Em-Up" and the following statements in its labeling were false and misleading: (Bottle label) "Stomachic and Stimulant to The Appetite"; (carton) "If this preparation is used according to directions, it will give beneficial results for the purposes or conditions for which it is recommended. The ingredients of this preparation are well and favorably known as meritorious and effective in conditions or for the purposes for which the preparation is recommended. * * * The formula * * * should prove beneficial if used according to instructions." The article would not be capable of fulfilling the promises of benefit stated and implied.

On August 4, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1484. Misbranding of 606 System Tonic. U. S. v. 100 Bottles and 16 Bottles of 606 System Tonic. Default decrees of condemnation and destruction. (F. D. C. Nos. 14030, 14031. Sample Nos. 68147-F, 68149-F.)

On October 13 and 17, 1944, the United States attorney for the Northern District of Ohio filed libels against 116 bottles of 606 System Tonic at Cleveland, Ohio, alleging that the article had been shipped between the approximate dates of May 19 and August 24, 1944, by the Aetna Chemical Co., Detroit, Mich.

Examination of samples showed that the article consisted essentially of water, alcohol, potassium iodide, and extracts of plant drugs, including a laxative plant drug.

The article was alleged to be misbranded in that the statements which appeared on the label, "Double Strength 606 System Tonic * * * For Tired and Run Down Condition * * * a Spring and Fall Tonic," were false and misleading since the article would not be effective as a system tonic, as a "Spring and Fall Tonic," or for a tired and run-down condition; and it would not constitute a treatment for syphilis, as the name and numerals "606" implied.

On December 19 and 21, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1485. Misbranding of Thujanoids Rectal Cones. U. S. v. 21 Cartons of Thujanoids Rectal Cones. Default decree of condemnation and destruction. (F. D. C. No. 13445. Sample No. 72897-F.)

On August 30, 1944, the United States attorney for the Northern District of California filed a libel against 21 cartons, each containing 2 dozen Thujanoids Rectal Cones, at San Francisco, Calif., alleging that the article had been shipped from New York, N. Y., by Akatos, Inc., on or about July 18, 1944.

Analysis showed that the article consisted essentially of mercurous iodide 0.138 grain per suppository, volatile oils, and extracts of plant drugs including hyoscyamus alkaloids.

The article was alleged to be misbranded in that the following statements on the leaflet in the cartons were false and misleading: "Prostatic Rectal Cones * * * for the purpose of relieving the distressing symptoms of enlarged Prostate Gland. * * * The treatment should be continued for at least six months. * * * In severe cases * * *. A marked recession, in the size of the gland, will be noted. * * * The early use of this treatment gives marked relief, and in many cases will avert the necessity of a prostatectomy; or of the distressing punch operation." The article would not be effective in the treatment of prostatic conditions. It was alleged to be misbranded further in that its label failed to state the quantity of mercurous iodide and hyoscyamus alkaloids present in the article.

On April 2, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1486. Misbranding of Esscolloid Detergent. U. S. v. 56 Packages of Esscolloid Detergent and All Labeling and Accompanying Circulars. Default decree of destruction. (F. D. C. No. 14420. Sample No. 87377-F.)

On November 15, 1944, the United States attorney for the District of Minnesota filed a libel against 56 packages of Esscolloid Detergent, including all labeling and accompanying circulars, at Minneapolis, Minn., alleging that the article had been shipped on or about October 10, 1944, by the Esscolloid Company, Inc., from New York, N. Y.

Examination of a sample disclosed that the article consisted essentially of material derived from psyllium seed and magnesium trisilicate.

The article was alleged to be misbranded in that certain statements on its labels and in the accompanying circulars entitled "Esscolloid Detergent" were false and misleading since they represented and suggested that the article was a detergent (a cleansing agent); that it was a gastro-intestinal neutralizer; that it was effective in the treatment of ulcers, disorders of the stomach, including gastric pain and distress, indigestion, inflammation, and bleeding; that it was effective in restoring loss of appetite and in overcoming nausea and bowel irritability; and that it was effective in improving digestive function and intestinal muscular weakness and in the treatment of constipation and the conditions resulting from faulty diet or overindulgence. The article was not a detergent; it was not a gastro-intestinal neutralizer; and it was not effective for the purposes stated and implied.

On February 14, 1945, no claimant having appeared, judgment was entered ordering that the product and all labeling be destroyed.

1487. Misbranding of Dr. Ledoux's Canadian Cough Syrup. U. S. v. 436 Bottles of Dr. Ledoux's Canadian Cough Syrup. Default decree of condemnation and destruction. (F. D. C. No. 14014. Sample No. 88434-F.)

On October 9, 1944, the United States attorney for the District of New Hampshire filed a libel against 436 bottles of the above-named product at Berlin, N. H., alleging that the article had been shipped on or about September 11, 1944, by the R. E. Marier Medicine Co., from Westbrook, Maine.

Examination showed that the article consisted essentially of sucrose and water with alcohol 0.3 percent, flavoring materials such as menthol and capsicum, a brown color, and an oily material. The article did not contain maple sugar, glycerine, or lemon juice; and it contained not more than a trace, if any, of honey.

The article was alleged to be misbranded because of false and misleading statements in its labeling regarding its efficacy in the relief of coughs, colds, sore throat, gripe, and after-cold effects. It was alleged to be misbranded further in that the label statement, "Ingredients are as follows: Maple Syrup, Honey, * * * Glycerine * * * Lemon Juice, 3½% Alcohol," was false and misleading.

On November 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1488. Misbranding of Ritamine Vitamin and Mineral Capsules. U. S. v. 937½ Dozen Boxes of Ritamine Vitamin and Mineral Capsules and 9 Packages of Booklets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14336. Sample Nos. 73761-F, 73762-F.)

On November 2, 1944, the United States attorney for the Southern District of California filed a libel against 937½ dozen boxes (various sizes) of Ritamine Vitamin and Mineral Capsules at Los Angeles, Calif., and 9 packages, each containing 300 copies, of a booklet entitled "Health Topics," which accompanied the article. It was alleged in the libel that the capsules were shipped between the approximate dates of January 26 and July 25, 1944, by the American Dietetics Co., Inc., from Yonkers, N. Y.

The article was alleged to be misbranded in that certain statements in the labeling were misleading. It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7916, in which are set forth in full the results of analyses, and the misleading statements referred to above.

On February 6, 1945, the American Dietetics Co., Inc., having admitted the allegations of the libel, and the case having been removed to the Eastern District of New York pursuant to agreement, judgment of condemnation was entered and it was ordered that the booklets be destroyed and that the remaining merchandise be released under bond for relabeling under the supervision of the Food and Drug Administration.

1489. Misbranding of Major Brand B Complex Vitamin Tablets. U. S. v. 15 Cases of Major Brand B Complex Vitamin Tablets. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 14398. Sample No. 80439-F.)

On November 8, 1944, the United States attorney for the Eastern District of Missouri filed a libel against 15 cases of the above-named product at St. Louis, Mo., alleging that the article had been shipped on or about July 24 and September 13, 1944, from New York, N. Y., by Major Vitamins, Inc.

The article was alleged to be misbranded in that certain labeling statements in the exhibit A attached to the libel were false and misleading. It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7914, in which are set forth in full the results of analyses, and the misleading statements in the exhibit A referred to above.

On December 18, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that all leaflets and display posters accompanying the product be destroyed, and that the product be delivered to a charitable institution.

1490. Misbranding of Walban Vitamin B Complex and Walban A, B₁, D, G (B₂) Vitamin Pearls. U. S. v. 35 Display Units of Walban Vitamin B Complex and 23 Display Units of Walban A, B₁, D, G (B₂) Vitamin Pearls. Default decrees of condemnation. Products ordered delivered to charitable institutions. (F. D. C. Nos. 13777, 13778. Sample Nos. 80616-F, 80617-F.)

On September 11, 1944, the United States attorney for the Eastern District of Missouri filed libels against 35 display units, each containing 12 packages of 30 pearls each, of Walban Vitamin B Complex and 23 display units, each containing 12 packages of 30 pearls each, of Walban A, B₁, D, G (B₂) Vitamin Pearls at St. Louis, Mo., alleging that the articles had been shipped on or about May 31, 1944, by the Walban Corporation, from Little Neck, Long Island, N. Y.

The products were alleged to be misbranded under Section 502 (a) in that certain statements in the labeling were false and misleading.

The vitamin B complex was alleged to be adulterated, and both products were alleged to be misbranded, under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7911, in which are set forth in full the false and misleading statements in the labeling referred to above.

On December 2 and 15, 1944, no claimant having appeared, judgments of condemnation were entered and the products were ordered delivered to charitable institutions after destruction of the leaflets, circulars, and display posters.

1491. Misbranding of Mi-Hair Scalp and Hair Preparations. U. S. v. 290 Bottles of Mi-Hair Scalp Medicine No. 1, 225 Bottles of Mi-Hair Scalp Medicine No. 2, 461 Bottles of Mi-Hair Shampoo, 469 Bottles of Mi-Hair Hair Conditioner and Scalp Invigorator, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 13834. Sample Nos. 73105-F, 73362-F to 73365-F, incl.)

On September 29, 1944, the United States attorney for the Southern District of California filed a libel against the above-mentioned articles and printed matter at Fresno, Calif., alleging that they had been shipped on or about May 10 and June 12, 1944, by Capillis, Inc., from Brooklyn, N. Y.

Analysis disclosed that the Scalp Medicine No. 1 contained water, isopropyl alcohol, and small amounts of betanaphthol, salicylic acid, resorcinol monoacetate, and sulfanilamide; that the Scalp Medicine No. 2 consisted of water, isopropyl alcohol, potassium carbonate, and small amounts of salicylic acid, betanaphthol, resorcinol monoacetate, and sulfanilamide; that the Mi-Hair Shampoo contained water, soap, and a trace of phenolic substances; and that the Mi-Hair Hair Conditioner and Scalp Invigorator contained small amounts of salicylic acid, betanaphthol, and resorcinol monoacetate incorporated in an ointment base composed of petrolatum and lanolin.

The articles were alleged to be misbranded because of false and misleading statements on their labels and in the printed matter (circulars, leaflets, and display placards) regarding the efficacy of the articles when used alone or in combination in the treatment of dandruff and in the stimulation of the scalp so as to increase the growth or prevent the loss of hair.

On October 30, 1944, no claimant having appeared, judgment of condemnation was entered and the products and the printed matter were ordered destroyed.

1492. Misbranding of Dr. Hibbard's Olive Vitalizer for Hair and Scalp. U. S. v. 116 Packages of Dr. Hibbard's Vitalizer for Hair and Scalp. Default decree of condemnation and destruction. (F. D. C. No. 13845. Sample No. 88020-F.)

On or about October 2, 1944, the United States attorney for the District of Connecticut filed a libel against 116 packages of the above-mentioned product at Middletown, Conn., alleging that it had been shipped on or about March 22 and July 13, 1944, by the Mulford Pharmacal Co., from Boston, Mass.

Examination showed that the article consisted essentially of mineral oil, water, and a small amount of sulfur and of boric acid, colored yellow.

The article was alleged to be misbranded (1) in that the label statement, "Olive Vitalizer for Hair and Scalp," was false and misleading as applied to the product, which contained no olive oil and which was not effective as a vitalizer for the hair and the scalp; (2) in that the label statement, "Active Ingredients Bayol, Boric Acid, Capsicum & Solution of Sulphur," was misleading since it created the impression that those ingredients would be effective in vitalizing the hair and scalp, and it failed to reveal the material fact that the product contained mineral oil; and (3) in that it failed to bear a label containing an accurate statement of the quantity of the contents since no statement of the quantity of the contents appeared on its label.

On November 28, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1493. Misbranding of Electric Vital Massager. U. S. v. Holdfast Truss Co. Plea of nolo contendere. Fine, \$250. (F. D. C. No. 14232. Sample No. 71238-F.)

On January 17, 1945, the United States attorney for the Northern District of California filed an information against the Holdfast Truss Co., a partnership, Oakland, Calif., alleging shipment of a quantity of the above-named product on or about April 14, 1944, from the State of California into the State of Oregon.

The article was an electrical device for massaging and applying heat to the prostate gland. It consisted of a plastic rod about 5 inches long, slightly enlarged and fluted at one end, containing a heating element.

The article was alleged to be misbranded in that certain statements on its label and in an accompanying circular entitled "Electric Vital Massager" were false and misleading since they represented and suggested that the article would be efficacious in the alleviation of pain caused by a disordered prostate gland; that it would produce the regenerative and the vitalizing results implied in the name "Vital Massager"; and that it would be efficacious in the cure, mitigation, treatment, and prevention of frequency of urination, either day or night, pain accompanying urination, urethral discharge, pain in the lower back, fullness or pressure in the rectum, acute susceptibility to worry and anxiety, the inclination to be melancholy, prostatitis, and the effects on the prostate of gonorrheal infection, alcoholism, sexual overindulgence, onanism, typhoid fever, smallpox, and similar conditions indicated and suggested by the abbreviation "etc."

On February 9, 1945, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$250.

DRUGS FOR VETERINARY USE*

1494. Misbranding of General Hog Liquid, General Hog Medicine "F," Poultry Tablets, and General Poultry Liquid. U. S. v. General Veterinary Laboratory. Plea of guilty. Fine, \$250 and costs. (F. D. C. No. 12540. Sample Nos. 5679-F to 5681-F, incl., 37846-F.)

On November 28, 1944, the United States attorney for the District of Nebraska filed an information against the General Veterinary Laboratory, a corporation, at Omaha, Nebr., alleging shipment of quantities of the above-named products between the approximate dates of November 10, 1942, and August 31, 1943, from the State of Nebraska into the States of Illinois and Iowa.

Analysis of a sample of the General Hog Liquid showed that the product was a light red-brown liquid with sediment of the same color. It contained, chiefly, water, sodium hydroxide, small amounts of phosphate and sulfate compounds of calcium, copper, and potassium; arsenic compounds; creosote and oil of Chenopodium; and a minute amount of strychnine (nux vomica indicated). The article was alleged to be misbranded in that certain statements in an accompanying circular entitled "Amazing Liquid Treats Sick, Wormy, Runty Hogs Without Taking Them Off Feed" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of all species of worms which infest hogs; that it would be efficacious in the prevention and treatment of sick and runty hogs and of disease germs which infest hogs, and in the treatment of necro, flu, and mixed infections; that it would cause bigger litters of pigs, would enable the user to raise every pig and bring pigs along fast and keep them free from worms and disease, would make pigs ready to sell earlier, enable the user to avoid sickness and losses, develop big frames and heavy bones in hogs, and prevent feed waste and low profits; and that it contained two ingredients which were effective wormers when used as directed, together with an ingredient which would promote appetite in sick

*See also No. 1462.

hogs, an ingredient which was an intestinal and lung antiseptic, an ingredient which would be efficacious for destroying disease germs when used as directed, and an ingredient which would help in the development of big bones and act as a blood purifier, aid digestion, promote appetite, and be valuable in the treatment of necro. The article would not be efficacious for the purposes recommended. It was alleged to be further misbranded (1) in that its label did not bear the common or usual name of each active ingredient, including the quantity and proportion of arsenic and strychnine contained in the article, since the list of ingredients borne on the bottle labels represented that each quart of the article contained 71 grains of arsenic and 0.0266 cc. of strychnine, whereas the article contained a smaller amount of arsenic than was declared, 60 grains of arsenic per quart, and a greater amount of strychnine than declared, 0.10 gram of strychnine per quart; and (2) in that the statements on the bottle label, "Extract of Nux Vomica (giving one quart of medicine 0.0266 cc. of strychnine), Solution of Potassium Arsenite 59.5% (giving one quart of medicine 71 gr. of arsenic)," were false and misleading since each quart of the article contained not more than 60 grains of arsenic and not less than 0.10 gram of strychnine.

Analysis of a sample of the General Hog Medicine "F" showed that the product was a clear, brown liquid with a small amount of black sediment. It contained, chiefly, ammonium chloride and phenol in aqueous solution. The article was alleged to be misbranded because of false and misleading statements on its labels which represented and implied that the article would be efficacious in the cure, mitigation, treatment, and prevention of symptoms of hog "Flu" (swine influenza) and coughs and bronchitis caused by colds.

Analysis of a sample of the Poultry Tablets showed that the product was a red lime-carbonate-coated tablet. It contained, chiefly, plant material and extracts, including a large amount of kamala, a small amount of nicotine, other plant material including a strychnine-bearing drug, and minute amounts of iron and sulfate. The article was alleged to be misbranded in that certain statements on the cans containing the article and in an accompanying circular entitled "Price List General Veterinary Products" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of roundworms, large tape worms, and pin worms; that it would remove all worms and cause poultry to grow and gain weight as they should; that it would increase egg production and prevent retarded growth, decreased egg profits, and disease resulting from worms in poultry; and that the article was an intestinal antiseptic which would tend to heal the intestines after removal of the worms and heal the avenues of disease infection. The article would not be efficacious for the purposes recommended.

Analysis of a sample of the General Poultry Liquid showed that it was a brown liquid (with light tan sediment) containing, chiefly, water, sodium hydroxide, calcium carbonate, an arsenic compound, small amounts of creosote and oil of Chenopodium, and a minute amount of a potassium compound. The article was alleged to be misbranded in that certain statements in an accompanying circular entitled "Price List General Veterinary Products" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of digestive and bowel troubles, respiratory diseases, worms, and other poultry troubles; that it would promote an extra degree of poultry health and vigor and make the poultry flock thrifty and profitable; that it would aid digestion and assimilation of food; that it would help build resistance to disease and ward off disease; that it would help keep large round worms out of poultry flocks; that it was a flock treatment which would prevent and successfully treat many common poultry ailments; that it was an intestinal antiseptic and tonic; and that it would be of value as a general treatment for sick birds. The article was not an intestinal antiseptic and tonic, and it would not be efficacious for the purposes recommended. It was alleged to be further misbranded in that the statement on the label, "Ingredients * * * Potassium Iodide," was false and misleading since it did not contain potassium iodide.

On December 19, 1944, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$100 on count 1 and \$50 on each of the remaining 3 counts, a total fine of \$250, plus costs.

1495. Misbranding of Midwest Vi-Tonic for Hogs. U. S. v. 9 Bags of Midwest Vi-Tonic for Hogs. Default decree of destruction. (F. D. C. No. 13839. Sample No. 67971-F.)

On October 4, 1944, the United States attorney for the Southern District of Ohio filed a libel against 9 100-pound bags of the above-mentioned product at London, Ohio, alleging that the article had been shipped on or about May 12, 1944, by the Midwest Mineral Co., Greenwood, Ind.

Analysis of a sample showed that the product consisted essentially of compounds of calcium, sodium and iron including phosphates, carbonates, sulfates and chlorides, charcoal and organic material including American wormseed and a trace of combined iodine. The article did not contain copper compounds.

The article was alleged to be misbranded in that certain statements on various labels and in an accompanying circular entitled "Midwest Vi-Tonic" were false and misleading since they represented and suggested that the article was effective in the prevention and treatment of the disease of hogs known as necro or necrotic enteritis and of pig troubles such as thumps and white scours, and in the treatment of indigestion, in regulating the bowels, and in relieving fever; that the product contained ingredients which possessed intestinal antiseptic value; and that the ingredients American wormseed, gentian, and fenugreek are tonics which would purify the blood stream and stimulate the liver and kidneys to throw off poisons. The article would not be efficacious for the purposes claimed; it did not contain ingredients which possessed intestinal antiseptic value; and American wormseed, gentian, and fenugreek are not tonics which would purify the blood stream and stimulate the liver and kidneys to throw off poisons.

On November 14, 1944, no claimant having appeared, judgment was entered ordering the product destroyed.

1496. Misbranding of Dr. David Roberts Worm Seed, Udder Balm, and Udderine. U. S. v. 69 Cartons of Worm Seed, 122 Cartons of Udder Balm, 21 Bottles of Udderine, and 600 Booklets. Default decree of condemnation and destruction. (F. D. C. No. 13779. Sample Nos. 71072-F, 71074-F, 71075-F.)

On or about September 19, 1944, the United States attorney for the District of Oregon filed a libel against 69 15-ounce packages of Worm Seed, 122 6-ounce cartons of Udder Balm, 21 4-ounce bottles of Udderine, and 600 booklets entitled "The Cattle Specialist," at Portland, Oreg., alleging that the articles had been shipped on or about May 18, 1944, by the Dr. David Roberts Veterinary Co., from Waukesha, Wis.

Microscopic examination of the Worm Seed showed that the article consisted of ground vegetable tissues, such as wheat grain, linseed, wormseed, corn grain, tobacco stems, quassia wood, licorice root, bean pod, and locust, together with mineral matter such as partially dried iron sulfate, copper sulfate, potassium nitrate, boric acid, and carbon particles such as charcoal. This examination did not show the presence of any male fern. Chemical analysis showed that the article contained 0.90 percent phenothiazine and 0.14 percent nicotine. The article was alleged to be misbranded in that certain statements on the carton label and in the accompanying booklet were false and misleading since they implied that the article contained male fern and phenothiazine in sufficient amounts to be an effective treatment for common worms which infest poultry and livestock, when administered in accordance with the directions in the labeling, whereas the article contained no male fern and but an insignificant amount of phenothiazine, and it would be of no value when used as directed for any species of worms which infest livestock and poultry.

Analysis of the Udder Balm showed that it was an ointment composed of saponifiable and unsaponifiable fatty matter, together with volatile oils such as turpentine, eucalyptus, and sassafras. Analysis of the Udderine showed that it was an emulsion consisting of water, chloroform, soap, ammonium chloride, and turpentine. Both articles were alleged to be misbranded in that certain statements on the carton labels and in the accompanying booklet were false and misleading since they implied that the articles, when used as directed, would be efficacious in the treatment of mastitis, caked and swollen udder, and other udder troubles of cows, whereas the articles, when used as directed, would have no value in the treatment of any disease condition of the udder of cows.

On November 8, 1944, no claimant having appeared, judgment of condemnation was entered and the products and booklets were ordered destroyed.

1497. Misbranding of Staley's Four Bells Worm Control Mash. U. S. v. 6 Sacks of Worm Control Mash. Default decree of condemnation and destruction. (F. D. C. No. 13772. Sample No. 67189-F.)

On September 21, 1944, the United States attorney for the District of Nebraska filed a libel against 6 100-pound sacks of Worm Control Mash at South Omaha, Nebr., alleging that the article had been shipped on or about December 2, 1943, by the Staley Milling Co., Kansas City, Mo. The article was labeled in part: "Staley's Four Bells Worm Control Mash."

Analysis of a sample disclosed that the article contained not more than 11 grains of nicotine per 100 pounds.

The article was alleged to be misbranded (1) because of false and misleading statements in its labeling regarding its efficacy in aiding the removal of large roundworms of chickens and turkeys; and (2) because the statement in its labeling, "Ingredients: * * * Nicotine (expressed as the alkaloid, 260 grains per 100 lbs. of feed)," was false and misleading.

On October 12, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1498. Misbranding of Aquilite. U. S. v. 39 Bottles of Aquilite. Default decree of condemnation and destruction. (F. D. C. No. 13396. Sample No. 58287-F.)

On September 1, 1944, the United States attorney for the District of Colorado filed a libel against 39 bottles, each containing 4 gallons, of Aquilite at Littleton, Colo., alleging that the article, which had been consigned by the Nathan W. Davis Laboratories, had been shipped on or about July 12, 1944, from Salt Lake City, Utah.

Analysis of a sample disclosed that the article consisted essentially of water with small amounts of asphalt and sulfonated petroleum derivatives.

The article was alleged to be misbranded in that the following statements in its labeling were false and misleading: "Poultry Health Insurance Aquilite is a modern chemical discovery which aids in controlling coccidiosis, bronchitis, sinitus, and 'blackhead' in turkeys; bronchitis and coccidiosis in chickens; pulorum diseases in both chickens and turkeys; and coccidiosis, 'spotted liver,' and 'sniffles' in rabbits * * * If flock is infected, use Aquilite * * * Those too sick to drink should be given it forcibly. * * * Treat sick birds." The article would be of no value in the prevention or treatment of any disease condition of poultry and rabbits.

On November 2, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1499. Misbranding of Apco Apcolene. U. S. v. 33 Bottles and 10 Bottles of Apco Apcolene. Default decree of condemnation and destruction. (F. D. C. No. 12961. Sample No. 72380-F.)

On July 19, 1944, the United States attorney for the Southern District of Iowa filed a libel against 33 1-pint bottles and 10 1-gallon bottles of Apco Apcolene at Ottumwa, Iowa, alleging that the article had been shipped on or about May 18, 1944, by the American Products Co., Inc., from Kansas City, Kans., and that certain labeling, which consisted of a diagnosis chart entitled "Take me with you and let me help you with your service work," a display card entitled "Raise More Meat Birds," and circulars entitled "Mycosis—Fungi" and "Fight Coccidiosis," had been shipped by that company on or about May 19, 1944, from Kansas City, Kans., to Ottumwa, Iowa, and that the labeling accompanied the article when it was introduced into and while it was in interstate commerce.

Analysis of samples disclosed that the article consisted chiefly of water and copper, iron, aluminum, magnesium, and manganese sulfate, colored with a red dye.

The article was alleged to be misbranded in that certain statements and pictures in its labeling which represented and suggested that the article was effective in the treatment and prevention of coccidiosis, blackhead, mycosis, and microscopic parasites were false and misleading since it would not be effective for such purposes.

On January 4, 1945, no claimant having appeared, judgment of condemnation was entered and it was ordered that the article and its labeling be destroyed.

1500. Misbranding of Coccidiosis 5-Drop Miracle for Chickens. U. S. v. 6 Bottles of Coccidiosis 5-Drop Miracle for Chickens. Default decree of condemnation and destruction. (F. D. C. No. 14021. Sample No. 84919-F.)

On October 10, 1944, the United States attorney for the District of Delaware filed a libel against 6 bottles of the above-named product at Bridgeville, Del.,

alleging that the article had been shipped on or about August 19, 1944, by Lewis' Laboratory, from East Providence, R. I.

Examination showed that the product contained approximately 0.105 gm. to 0.125 gm. strychnine per 100 cc. of the article.

The article was alleged to be misbranded because of false and misleading statements in its labeling regarding its efficacy in the prevention and cure of coccidiosis in chickens, in increasing egg production, in building up run-down birds, and in increasing weight of broilers.

On November 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1501-1550

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., April 17, 1946.

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PRODUCTS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

1501. Misbranding of Pan-Secretin. U. S. v. 144 Bottles of Pan-Secretin. Default decree of condemnation and destruction. (F. D. C. No. 12776. Sample Nos. 41205-F, 60873-F.)

On July 5, 1944, the United States attorney for the Northern District of Texas filed a libel against 144 bottles of Pan-Secretin at Dallas, Tex., alleging that the article had been shipped by the Harrower Laboratory, Inc., from Glendale, Calif., between the approximate dates of March 27 and June 5, 1944. The article was labeled in part: "Formula: Pancreas Substance (Tail) gr. 3½; Duodenal Substance, gr. 1½; Excipient q. s."

The article was alleged to be misbranded in that it was a drug composed partly of insulin that was not from a batch for which a certificate or release had been issued pursuant to the law.

On August 12, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1504, 1510, 1512, 1516; deceptive packaging, No. 1547; failure to bear an accurate statement of the quantity of the contents, Nos. 1504, 1505, 1516; failure to bear the name and place of business of the manufacturer, packer, or distributor, Nos. 1511, 1516; failure to comply with the labeling requirements of an official compendium, No. 1526; cosmetic, subject to the drug provisions of the Act, No. 1503.

1502. Misbranding of Pancreas Cell Compound. U. S. v. 4 Bottles of Pancreas Cell Compound. Default decree of condemnation and destruction. (F. D. C. No. 15281. Sample No. 29384-H.)

On February 23, 1945, the United States attorney for the Northern District of California filed a libel against 4 bottles of Pancreas Cell Compound at San Francisco, Calif., alleging that the article had been shipped on or about November 27, 1944, from South Bend, Ind., by the Oak Balm Co., Inc. The article was labeled in part: "Directions Take one or two tablets just before eating, three times daily, or according to special directions from your doctor."

Examination of a sample showed that the article contained glandular material including pancreatin and insulin.

The article was alleged to be misbranded (1) in that it was a drug composed partly of insulin that was not from a batch for which a certificate or release had been issued; and (2) in that the statement on the bottle label, "A pluri-endocrine compound of carefully selected endocrine substances designed to act as a glandular stimulant," was false and misleading since the article would not act as a glandular stimulant. The article was alleged to be misbranded further in that the label statement, "Pancreas Cell Compound Each Tablet Contains Pancreas Substance. . . . 1 Grain Islets of Langerhans . . . 2 Grains Parathyroid Substance . . . $\frac{1}{20}$ Grain And small amounts of Orchic, Spleen, Parotid and Submaxillary Substances," was misleading in the absence of a revelation of the fact, material in the light of such representation and material with respect to the consequences which might result under the conditions of use prescribed in the labeling, that none of the ingredients listed nor the combination of them would have any therapeutic effect if consumed in accordance with the directions stated upon the bottle label.

On March 31, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1503. Misbranding of Blemo Ointment. U. S. v. 5½ Dozen Packages of Blemo Ointment. Default decree of condemnation and destruction. (F. D. C. No. 14196. Sample No. 90100-F.)

On November 6, 1944, the United States attorney for the Southern District of Iowa filed a libel against 5½ dozen packages of Blemo Ointment at Moravia, Iowa, alleging that the article had been shipped on or about May 27, 1944, from Canton, Ohio, by the Blemo Co.

Examination of samples disclosed that the article consisted essentially of mercuric oxide, benzoin, and an ointment base, together with material obtained from pine.

The article was alleged to be misbranded (1) in that the statements on its labels, "itching, or burning of eczema, acne * * * blotches, scales, pimples, * * * skin-itch and other externally caused skin irritations," were false and misleading since the article would not be effective in the treatment of those conditions; and (2) in that its label failed to bear adequate directions for use since it did not bear directions for the treatment of impetigo.

On December 30, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1504. Misbranding of Ger-Oil. U. S. v. 29½ Dozen Bottles and 2 Dozen Bottles of Ger-Oil. Default decree of condemnation and destruction. (F. D. C. No. 15163. Sample Nos. 22502-H, 22517-H.)

On February 1, 1945, the United States attorney for the Western District of Tennessee filed a libel against 29½ dozen large bottles and 2 dozen small bottles of Ger-Oil at Memphis, Tenn., alleging that the article had been shipped between the approximate dates of November 8, 1944, and January 4, 1945, by the Ger-Oil Co., from Jonestown, Miss.

Analysis showed that the article consisted of sulfur, turpentine, and a saponifiable oil.

The article was alleged to be misbranded (1) in that its label failed to bear any statement of the quantity of the contents; (2) in that it was fabricated from two of more ingredients and its label failed to bear the common or usual name of each active ingredient; and (3) in that its labeling failed to bear adequate directions for use, since there were no directions for use.

On April 11, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUG ACTIONABLE BECAUSE OF THE PRESENCE OF A NONCERTIFIED COAL-TAR COLOR

1505. Adulteration and misbranding of Burma Foot Cream. U. S. v. 28 Jars of Burma Foot Cream. Default decree of condemnation and destruction. (F. D. C. No. 12902. Sample No. 68109-F.)

On July 10, 1944, the United States attorney for the Northern District of Ohio filed a libel against 28 jars of Burma Foot Cream at Akron, Ohio, alleging that the article had been shipped on or about April 14, 1944, by the Belmont Co., Springfield, Mass. The article was labeled in part: "Burma Foot Cream * * * Green Food Color."

Examination of a sample disclosed that the article contained a noncertified dye, dimethylaminoazobenzene, more commonly known as Butter Yellow, Colour Index No. 19; and that the label of the article bore no statement of the quantity of the contents.

The article was alleged to be adulterated in that it was a drug that contained, for purposes of coloring only, a green coal-tar color that had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified.

The article was alleged to be misbranded (1) in that the label statement "Green Food Color" was misleading as applied to an article containing a color unfit for use in foods; and (2) in that it failed to bear a label containing an accurate statement of the quantity of contents.

On August 8, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1506. Adulteration of isopropyl alcohol compound. U. S. v. 131¼ Dozen Bottles of Isopropyl Alcohol Compound. Default decree of condemnation and destruction. (F. D. C. No. 15617. Sample No. 24323-H.)

On March 10, 1945, the United States attorney for the Eastern District of Louisiana filed a libel against 131¼ dozen bottles of isopropyl alcohol compound at New Orleans, La., alleging that the article had been shipped on or about August 19, 1944, by the Border States Distributing Co., from Houston, Tex. The article was labeled in part: "One Pint St. Francis Rubbing Isopropyl Alcohol Compound 70% By Volume."

Examination of the article disclosed that the isopropyl alcohol content was approximately 46 percent by volume in some bottles and approximately 62 percent by volume in other bottles.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, i. e., isopropyl alcohol 70 percent.

On April 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1507. Adulteration of isopropyl alcohol compound. U. S. v. 27¼ Dozen Bottles of Isopropyl Alcohol Compound. Default decree of condemnation and destruction. (F. D. C. No. 15483. Sample No. 24272-H.)

On March 8, 1945, the United States attorney for the Eastern District of Louisiana filed a libel against 27¼ dozen bottles of isopropyl alcohol compound at New Orleans, La., alleging that the article had been shipped on or about January 17, 1945, by the R. & R. Products Co., from Corpus Christi, Tex. The article was labeled in part: "R & R Hospital Brand Isopropyl Alcohol Compound Hospital Grade Isopropyl Alcohol 70% * * * 1 Fl. pint."

Examination showed that the article contained not more than 38.6 percent by volume of isopropyl alcohol.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, i. e., isopropyl alcohol 70 percent.

On April 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1508. Adulteration and misbranding of solution of epinephrine hydrochloride. U. S. v. 52 Vials and 168 Bottles of Solution of Epinephrine Hydrochloride. Default decrees of condemnation and destruction. (F. D. C. Nos. 15074, 15152, 15384. Sample Nos. 85403-F, 6266-H, 22313-H, 22314-H.)

On January 19 and February 14 and 15, 1945, the United States attorneys for the Eastern District of Pennsylvania, the District of New Jersey, and the East-

ern District of Missouri filed libels against the following quantities of the above-named product: 52 vials at Philadelphia, Pa., 57 vials at Irvington, N. J., and 168 bottles at St. Louis, Mo., alleging that the article had been shipped between the approximate dates of November 8, 1944, and January 18, 1945, by the Premo Pharmaceutical Laboratories, Inc., from New York, N. Y. The article was labeled in part: "1 Fld. Oz. Premo Vasodrine Solution of Epinephrine Hydrochloride U. S. P. 1-1000."

The United States Pharmacopoeia provides that solution of epinephrine hydrochloride has a potency equivalent to a solution containing 1 gram of U. S. P. Epinephrine Reference Standard in each 1,000 cc. Examination showed that the article had an activity of from 27 to 45 percent of that claimed upon its label and required by the Pharmacopoeia.

The article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia XII, and its strength differed from the standard set forth therein.

It was alleged to be misbranded in that the statement on its label, "Solution of Epinephrine Hydrochloride U. S. P. 1-1000," was false and misleading as applied to the article.

Between February 13 and April 2, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1509. Adulteration and misbranding of estrogenic hormones in oil. U. S. v. 3 Bottles of Estrogenic Hormones. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14868. Sample No. 78195-F.)

On December 26, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 3 bottles containing a total of approximately 5,300 cc. of estrogenic hormones at Philadelphia, Pa., alleging that the article had been shipped on or about October 4 and 16, 1944, from Chicago, Ill., by the W. F. Straub and Co.

Examination disclosed that the potency of the article was equivalent to not more than 12,000 International Units of estrone per cubic centimeter.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, 20,000 International Units of estrogenic ovarian follicular hormones.

The article was alleged to be misbranded in that the statements on its label, "Whole Natural Estrogenic Hormones From Pregnant Mare's Urine Consisting Mainly of Estrone and Estradiol in Sesame Oil 20,000 IU/CC," were false and misleading since the potency of the article was materially less than was represented.

On March 2, 1945, W. F. Straub and Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1510. Adulteration and misbranding of estrogenic hormone injection. U. S. v. 326 Vials of Estrogenic Hormone Injection. Default decree of condemnation and destruction. (F. D. C. No. 15314. Sample No. 83315-F.)

On February 24, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 326 vials of estrogenic hormone injection at Philadelphia, Pa. It was alleged in the libel that the article had been repackaged by the consignee at Philadelphia, Pa., from bulk material contained in 5 1-liter bottles which had been shipped to it by Halfdan Hebo, from New York, N. Y., on or about May 20, 1944.

The article in the 1-liter bottles was labeled in part: "Biologically tested Estrogenic Substance in Propylene Glycol, 10,000 I. U. per ml." The article in the vials was labeled in part: "Injection Estrogenic Hormone * * * Each cc. contains Estrogenic Hormone 10,000 I. U., obtained from pregnant mares' urine, consisting principally of estrone and estradiol, with Chlorobutanol * * * 1.5% in sterile propylene glycol."

Examination of a sample taken from the repackaged material showed that the article contained estrogenic steroids consisting of compounds including little or no estrone, together with the inert substance cholesterol.

The article was alleged to be adulterated in that a substance containing estrogenic material including little or no estrone and the inert compound cholesterol

had been substituted in whole or in part for natural estrogenic hormones in approximately the proportions in which they are present in the animal system and not broken down to estradiol.

The article was alleged to be misbranded in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

On April 3, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1511. Adulteration and misbranding of estrogenic hormones in oil. U. S. v. 9,500 Cubic Centimeters of Estronegenic Hormones in Oil. Default decree of condemnation and destruction. (F. D. C. No. 15270. Sample No. 82813-F.)

On February 14, 1945, the United States attorney for the District of New Jersey filed a libel against 9,500 cc. of the above-named product at Bloomfield, N. J., alleging that the article had been delivered on or about April 12, 1944, by the Unified Laboratories, Inc., in New York, N. Y., to an agent of the Lehn and Fink Products Corp., and was transported by that agent on the same date to Bloomfield, N. J. The article was invoiced as "Sesame Oil containing 50,000 International Units of Estrogens (Natural) per cubic centimeter." The only labels which the article bore when it was transported in interstate commerce were stickers bearing various numbers indicating in cubic centimeters the quantity of the contents at various levels of the bottle.

Examination of a sample showed that the article contained an insignificant proportion, if any, of estrone.

It was alleged to be adulterated in that substances other than estrogens derived from natural sources had been substituted in whole or in part for estrogens (natural). The article was alleged to be misbranded (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and (2) in that its label failed to bear the common or usual name of its active ingredients.

On March 26, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1512. Adulteration and misbranding of estrogenic substance in sesame oil. U. S. v. 2 Filled Bottles and One Partly Filled Bottle of Estrogenic Substance in Sesame Oil. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 15268. Sample No. 85231-F.)

On February 12, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2 filled bottles and one partly filled bottle of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about November 27, 1944, from Maspeth, N. Y., by the Hema Drug Co., Inc. The article was invoiced as "Natural Estrogenic Hormone in Sesame Oil."

Examination of a sample disclosed that the article contained an estrus-producing hormone, including little, if any, estrone.

It was alleged to be adulterated in that substances other than natural estrogenic hormones in sesame oil had been substituted in whole or in part for natural estrogenic hormones in sesame oil. It was alleged to be misbranded in that its label failed to bear the common or usual names of its active ingredients.

On April 24, 1945, the Hema Drug Co., Inc., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1513. Adulteration of lubricating jelly. U. S. v. 23½ Dozen Tubes of Lubricating Jelly. Default decree of condemnation and destruction. (F. D. C. No. 15164. Sample No. 74315-F.)

On January 25, 1945, the United States attorney for the Southern District of California filed a libel against 23½ dozen tubes of lubricating jelly at Los Angeles, Calif., alleging that the article had been shipped on or about November 3, 1944, by the McNeil Laboratories, from Philadelphia, Pa. The article was labeled in part: "Lubricant A Sterile * * * Jelly."

Examination showed that the article was not sterile but was contaminated with living micro-organisms.

It was alleged to be adulterated in that its purity and quality fell below that which it purported or was represented to possess.

On March 13, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1514. Adulteration of sodium citrate. U. S. v. 18 Bottles of Sodium Citrate. Default decree of condemnation and destruction. (F. D. C. No. 14495. Sample No. 62349-F.)

On November 28, 1944, the United States attorney for the Western District of Louisiana filed a libel against 18 bottles of sodium citrate at Shreveport, La., alleging that the article had been shipped on or about August 25, 1944, by the Continental Hospital Service, Cleveland, Ohio. The article was labeled in part: "70 cc. Sodium Citrate 2½% W/V in Isotonic Solution of Sodium Chloride."

The article was alleged to be adulterated in that it purported to be sterile anti-coagulant solution of sodium citrate for parenteral use, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not free from turbidity and undissolved material.

On February 20, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1515. Adulteration and misbranding of thiamine chloride solution. U. S. v. 64 Vials of Thiamine chloride solution. Default decree of condemnation and destruction. (F. D. C. No. 15088. Sample No. 85237-F.)

On January 23, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 64 vials, each containing 30 cc., of thiamine chloride solution at Philadelphia, Pa., alleging that the article had been shipped on or about December 14, 1944, from New York, N. Y., by the Bellevue Laboratories, Inc.

The vials containing the article were unlabeled, and there was no agreement between the shipper and the consignee regarding labeling.

The article was alleged to be adulterated in that it was an ampuled solution of thiamine chloride, and its quality fell below that which it purported and was represented to possess since it was contaminated with undissolved material and therefore was not suitable for parenteral administration.

The article was alleged to be misbranded (1) in that its label failed to bear the name and place of business of the manufacturer, packer, or distributor, or an accurate statement of the quantity of contents; and (2) in that its label failed to bear the common or usual name of each active ingredient and, whether active or not, the name and quantity or proportion of chlorobutanol, a chloroform derivative, which was contained in the article.

On February 13, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1516. Adulteration and misbranding of vitamin K. U. S. v. 364 Cartons of Menadione Sodium Bisulfite Addition Product. Default decree of condemnation and destruction. (F. D. C. No. 14633. Sample No. 63649-F.)

On December 12, 1944, the United States attorney for the Northern District of Georgia filed a libel against 364 cartons, each containing 6 ampuls, 1-cc. size, of the above-named article at Atlanta, Ga., alleging that the article had been shipped on or about November 8, 1944, by the U. S. Standard Products Co., from Woodworth, Wis.

The United States Pharmacopoeia (twelfth revision) requires that menadione sodium bisulfite injection shall contain an amount of menadione equivalent to not less than 47 percent of the labeled amount of menadione sodium bisulfite.

The article was alleged to be adulterated in that it purported to be and was represented as menadione sodium bisulfite injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard since it contained an amount of menadione equivalent to not more than 37.1 percent of the labeled amount of menadione sodium bisulfite.

The article was alleged to be misbranded in that the label statement, "Each 1 cc. contains 3.8 Mg. * * * Menadione Sodium Bisulfite Addition Product (Equivalent in activity to 2 Mg. Menadione)," was false and misleading since the article contained in each 1-cc. ampul not more than 2.68 milligrams of menadione sodium bisulfite, or not more than 1.41 milligrams of menadione.

On April 20, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1517. Adulteration and misbranding of vitamin K. U. S. v. 364 Cartons of Vitamin K (and 3 other seizure actions against vitamin K). Default decrees of condemnation. Portion of product ordered delivered to a charitable organization; remainder ordered destroyed. (F. D. C. Nos. 14888, 14889, 14906, 15052. Sample Nos. 84131-F, 90802-F, 90803-F, 90817-F, 99125-F.)

Between January 3 and 12, 1945, the United States attorneys for the Eastern District of Missouri, the Northern and Southern Districts of Ohio, and the North-

ern District of California filed libels against 364 cartons at St. Louis, Mo., 6,788 cartons at Columbus, Ohio, 1,564 cartons at Toledo, Ohio, and 728 cartons at San Francisco, Calif., each carton containing 6 ampuls of vitamin K. It was alleged that the article had been shipped on or about November 8, 1944, from Woodworth, Wis., by the U. S. Standard Products Co. The article was labeled in part: (Ampul) "1 cc size Ampul Vitamin K Water Soluble (Synthetic) Ampullae Menadioni, 3.8 mg. (Equiv. 2 mg. Menadione)."

The article was alleged to be adulterated in that it purported to be and was represented as menadione sodium bisulfite injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard, which requires that menadione sodium bisulfite injection shall contain an amount of menadione equivalent to not less than 47 percent of the labeled amount of menadione sodium bisulfite, whereas the article contained menadione in amounts varying from 38 percent to 44 percent of the labeled amount.

The article was alleged to be misbranded in that the statement on its label, "1 cc size Ampul * * * Ampullae Menadioni * * * 3.8 mg. (Equiv. 2 Mg. Menadione)," was false and misleading since the article contained, in each 1-cc. ampul, menadione sodium bisulfite in amounts varying from 2.73 milligrams to 3.15 milligrams, or menadione in amounts varying from 1.45 milligrams to 1.66 milligrams.

Between February 10 and March 31, 1945, no claimant having appeared, judgments of condemnation were entered and a portion of the product was ordered delivered to a charitable organization and the remainder was ordered destroyed.

1518. Adulteration of cramp bark. U. S. v. 4 Bags, 3 Full Barrels, and 1 Partly Filled Barrel of Cramp Bark. Default decree of condemnation and destruction. (F. D. C. No. 15079. Sample Nos. 93713-F, 6301-H.)

On January 22, 1945, the United States attorney for the Eastern District of New York filed a libel against the above-mentioned quantities of cramp bark at Brooklyn, N. Y. It was alleged in the libel that 11 bags containing a total of 820 pounds of the article, labeled, in part, "Cramp Bark True N. F.," had been shipped on or about November 4, 1944, by the St. Louis Commission Co., from St. Louis, Mo.; that thereafter the article in 7 of the bags was ground up and placed in 3 full barrels and 1 partly filled barrel labeled, in part, "Granulated Cramp Bark True N. F. For Manufacturer's Use"; and that the labels on the remaining 4 bags of unground material were changed by stamping the word "Non-Official" over the initials "N. F."

Examination of samples of the ground and unground material showed that the article did not consist of cramp bark but consisted of the bark of a species of maple, such as *Acer Spicatum*.

The article was alleged to be adulterated in that another substance had been substituted for it.

On March 12, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1519. Adulteration of dandelion roots. U. S. v. 50 Bags of Dandelion Roots. Default decree of condemnation and destruction. (F. D. C. No. 15139. Sample No. 5945-H.)

On February 6, 1945, the United States attorney for the District of New Jersey filed a libel against 50 bags containing approximately 2,955 pounds of dandelion roots at Jersey City, N. J., alleging that the article had been shipped on or about January 2, 1945, from New York, N. Y., by the Kachurin Drug Co.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard, which requires that vegetable drugs are to be as free as practicable from molds, insects, or other animal life and animal excreta and shall show no evidence of deterioration, since it was contaminated with mold and rot, had been eaten by insects, and was also contaminated with insect excreta.

On April 2, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1520. Adulteration of senna siftings. U. S. v. 1 Bale of Senna Siftings. Default decree of condemnation and destruction. (F. D. C. No. 14909. Sample No. 90644-F.)

On or about January 9, 1945, the United States attorney for the Northern District of Ohio filed a libel against 1 bale containing approximately 370 pounds of senna siftings at Cleveland, Ohio, alleging that the article had been shipped

on or about May 1, 1944, by S. B. Penick & Co., Lyndhurst, N. J. The article was labeled in part: "Crude Drugs."

Examination of a sample disclosed that the article contained substantial amounts of dead insects, insect larvae, cast skins of insects, insect fragments, and insect excreta.

It was alleged to be adulterated in that it purported to be senna (senna siftings), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity fell below the standard set forth therein since it was not substantially free from insects, extraneous animal material, or animal excreta.

On February 28, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1521. Adulteration and misbranding of water for injection. U. S. v. 850 Ampuls of Water for Injection. Default decree of condemnation and destruction. (F. D. C. No. 14874. Sample Nos. 82086-F, 82895-F.)

On December 29, 1944, the United States attorney for the Eastern District of New York filed a libel against 850 20-cc. ampuls of water for injection at Long Island City, N. Y., alleging that the article had been shipped on or about September 27, 1944, by Sharp and Dohme, Inc., from Philadelphia, Pa.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity fell below the standard set forth therein since it was contaminated with living mold.

The article was alleged to be misbranded in that the statement on its labels, "Sterile," was false and misleading.

On March 5, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1522. Adulteration of triple distilled water. U. S. v. 1,900 Ampuls of Triple Distilled Water. Default decree of forfeiture and destruction. (F. D. C. No. 15120. Sample No. 12901-H.)

On February 7, 1945, the United States attorney for the Southern District of Indiana filed a libel against 1,900 ampuls of triple distilled water at Indianapolis, Ind., alleging that the article had been shipped on or about August 18, 1944, by the Torigan Laboratories, Inc., from Queens Village, N. Y.

The article was alleged to be adulterated in that it purported to be and was represented as water for injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it failed to meet the requirement of the pyrogen test described in the Pharmacopoeia.

On March 31, 1945, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1523. Adulteration and misbranding of adhesive strips. U. S. v. 18 Dozen Cartons of Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 15147. Sample No. 6312-H.)

On February 7, 1945, the United States attorney for the Southern District of New York filed a libel against 18 dozen cartons of adhesive strips at New York, N. Y., alleging that the article had been shipped on or about October 26 and November 8, 1944, by the Hampton Manufacturing Co., Carlstadt, N. J. The article was labeled in part: "Blue Cross Adhesive Strips * * * Sterilized."

The article was alleged to be adulterated in that it purported to be adhesive absorbent gauze (adhesive absorbent compress), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity fell below the standard set forth therein since it was not sterile but was contaminated with spore-bearing aerobic bacteria, and its difference in purity from the standard was not plainly stated on the label.

It was alleged to be misbranded in that the label statement, "Sterilized," was false and misleading as applied to an article which was not sterile but was contaminated with viable bacteria.

On March 12, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1524. Adulteration of adhesive strips. U. S. v. 79½ Gross of Adhesive Strips. Default decree of condemnation. Product ordered sold. (F. D. C. No. 15122. Sample No. 63662-F.)

On January 30, 1945, the United States attorney for the Northern District of Georgia filed a libel against 79½ gross of adhesive strips at Atlanta, Ga., alleging that the article had been shipped on or about December 1, 1944, by the Ross

Products Co., Inc., from New York, N. Y. The article was labeled in part: "Home-aid * * * Adhesive Strips."

Examination of a sample showed that the article was not sterile but was contaminated with living micro-organisms. The weight of the compress was one-half of that of a compress of the same area composed of four layers of type I absorbent gauze, as described in the United States Pharmacopoeia.

The article was alleged to be adulterated in that it purported to be adhesive absorbent compress, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality fell below the standard set forth therein since the article was not sterile and the weight of the compress was less than that of a compress of the same area composed of four layers of type I absorbent gauze, and its difference in quality and purity from the official standard was not plainly stated on the label.

On May 1, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered sold on condition that the packages be stamped "Not sterilized and not to be used on open wounds or as a surgical dressing." The product was not to be resold by the purchaser.

1525. Adulteration and misbranding of bandages. U. S. v. 191 Units and 190 Units of Bandages. Default decree of condemnation and destruction. (F. D. C. No. 7460. Sample Nos. 92537-E, 92538-E.)

On May 5, 1944, the United States Attorney for the Southern District of California filed a libel against 191 units and 190 units of bandages at Los Angeles, Calif., alleging that the article had been shipped between the approximate dates of January 7 and March 16, 1942, by the Medical Supply Co., from Chicago, Ill.; and charging that it was misbranded. The article was labeled in part: "40 Inch Triangular Bandages Sterilized," or "2 inch Compress Bandage."

Examination of samples disclosed that the article was not sterile but was contaminated with living micro-organisms.

The article was alleged to be adulterated in that its quality and purity fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that the statement "Sterilized," on the label of each lot of the article, and the statement "Can also be used as a sterile compress in the absence of a compress bandage," on the label of the 191-unit lot, were false and misleading as applied to an article contaminated with living micro-organisms.

On July 11, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1526. Adulteration and misbranding of gauze bandage. U. S. v. 19 Cartons of Gauze Bandages. Default decree of condemnation and destruction. (F. D. C. No. 15302. Sample No. 2246-H.)

On March 5, 1945, the United States attorney for the Eastern District of North Carolina filed a libel against 19 cartons, each containing 12 packages, of gauze bandages at Wilson, N. C., alleging that the article had been shipped on or about January 5, 1945, by the Elliott Sales Co., from Rome, Ga. The article was labeled in part: (Package) "Gauze Bandage 2 Inch, 8 Yds. Best Products Co. of America Distributors New York, N. Y."

Examination of samples disclosed that the article was contaminated with living micro-organisms, and that each package contained 2 rolls of gauze bandage, 1 inch x 8 yards.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile.

It was alleged to be misbranded in that it was not labeled as prescribed in the United States Pharmacopoeia since the Pharmacopoeia provides that the width and length of the bandage shall be stated on the package, and the statement on the label of the article, "2 Inch, 8 Yds.," was incorrect.

On April 17, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1527. Adulteration of prophylactics. U. S. v. 49 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 15178. Sample No. 22105-H.)

On January 30, 1945, the United States attorney for the Eastern District of Missouri filed a libel against 49 gross of prophylactics at St. Louis, Mo., alleging that the article had been shipped on or about December 19, 1944, from Chicago,

Ill., by the Berg Sales Co. The article was labeled in part: "Texide Rubber Sheaths."

Examination showed that the article was defective in that it contained holes.

The article was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess.

On March 1, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed to the extent that it would be suitable only for salvage rubber.

1528. Adulteration and misbranding of prophylactics. U. S. v. 46 Gross Prophylactics (and 3 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 15236, 15241, 15467, 15615. Sample Nos. 10425-H, 18321-H, 18322-H, 29041-H, 31408-H.)

Between February 13 and March 13, 1945, the United States attorneys for the District of Minnesota, the Western District of Pennsylvania, and the Northern and Southern Districts of California filed libels against the following quantities of prophylactics: 46 gross at Minneapolis, Minn., 24 gross at Pittsburgh, Pa., 195 dozen at San Francisco, Calif., and 5 gross at Los Angeles, Calif.; alleging that the article had been shipped between the approximate dates of October 25, 1944, and February 14, 1945, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo., and Kansas City, Mo. The article was labeled in part: "Sekurity Prophylactics." "Dean's Genuine Reservoir End Parisian," "Ultrex Economy Package," or "Dean's Peacocks."

Examination of samples disclosed that the article was defective in that it contained holes.

It was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess.

The article was alleged to be misbranded in that the following label statements were false and misleading as applied to an article containing holes: (Sekurity brand) "Sekurity Prophylactics * * * Sekurity's are tested on new, modern equipment for your protection * * * An aid in preventing venereal diseases"; (Parisian brand) "Devices for use as an aid in Preventing Venereal Diseases. Guaranteed 2 years against Deterioration * * * Medical science wages an unceasing battle against disease and one of its most important and effective weapons is rubber devices * * * why buy inferior devices and take chances, your health comes first * * * Devices are individually Air Blown tested and inspected under strong lights for your Protection. Insist on Dependable Protection," "An aid in preventing Venereal disease. Guaranteed for 2 years against deterioration. Every individual Parisian is carefully selected and tested," and "For your Health's Sake * * * selected prophylactic * * * a reliable safeguard for your health"; (Ultrex brand) "Scientifically Tested," and "Ultimate of Quality"; and (Peacock brand) "Tested," "for your protection," and "An aid in preventing venereal diseases."

Between March 29 and June 13, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1529. Adulteration and misbranding of prophylactics. U. S. v. 45½ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 15271. Sample No. 5637-H.)

On or about February 12, 1945, the United States attorney for the District of Connecticut filed a libel against 45½ gross of prophylactics at New Haven, Conn., alleging that the article had been shipped on or about January 16, 1945, by the Universal Merchandise Co. (Gotham Sales Co.), New York, N. Y. The article was labeled in part: "XCello's Prophylactics."

Examination of samples disclosed that the article was defective in that it contained holes.

It was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded in that the label statement "Prophylactics" was false and misleading when applied to an article containing holes.

On March 14, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1530. Adulteration and misbranding of prophylactics. U. S. v. 23¼ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 15449. Sample No. 29055-H.)

On March 1, 1945, the United States attorney for the Northern District of California filed a libel against 23¼ gross of prophylactics at San Francisco, Calif., alleging that the article had been shipped on or about September 22 and October

6, 1944, by the Walgreen Drug Stores, from Chicago, Ill. The article was labeled in part: "Derbies Manufactured for Jay Dee Drug Co., Chicago, Ill. By the Killian Manufacturing Co., Akron, Ohio."

Examination of samples disclosed that the article was defective in that it contained holes.

It was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded in that the label statement, "for the prevention of Disease," was false and misleading as applied to an article containing holes.

On March 31, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1531. Adulteration and misbranding of prophylactics. U. S. v. 44 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 14927. Sample No. 62324-F.)

On December 30, 1944, the United States attorney for the Northern District of Alabama filed a libel against 44 gross of prophylactics at Birmingham, Ala., alleging that the article had been shipped on or about October 30, 1944, from New York, N. Y., by the World Merchandise Exchange. The article was labeled in part: "Silver-Tex Prophylactics * * * Manufactured by The Killian Mfg. Company Akron, Ohio."

Examination of samples showed that the article was defective in that it contained holes.

It was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded in that the label statement, "Prophylactics," was false and misleading as applied to an article containing holes.

On January 30, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1532. Adulteration and misbranding of prophylactics. U. S. v. 47½ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 15132. Sample No. 5629-H.)

On or about January 31, 1945, the United States attorney for the District of Connecticut filed a libel against 47½ gross of prophylactics at New Haven, Conn., alleging that the article had been shipped on or about January 10, 1945, from New York, N. Y., by the Goodwear Rubber Co. The article was labeled in part: "Xcello's Prophylactics."

Examination of samples disclosed that the article was defective in that it contained holes.

It was alleged to be adulterated in that its quality fell below that which it purported and was represented to possess. It was alleged to be misbranded in that the label statement, "Prophylactics," was false and misleading as applied to an article containing holes.

On March 13, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1533. Misbranding of Pierre Cartier's Medicine. U. S. v. 199 Bottles of Pierre Cartier's Medicine. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15286. Sample No. 11421-H.)

On February 20, 1945, the United States attorney for the District of Rhode Island filed a libel against 199 bottles of Pierre Cartier's Medicine at Providence, R. I., alleging that the article had been shipped on or about January 9 and 31, 1945, from Palmer, Mass., by the Bay State Drug Co.

Examination showed that the article consisted essentially of a mixture of equal volumes of cod liver oil, rum, and honey.

It was alleged to be misbranded in that certain statements on its label and in a circular entitled "Pierre Cartier's Medicine," which was enclosed in the retail carton with the bottle, were false and misleading since they represented and suggested that the article would be effective in the treatment and prevention of colds and diseases resulting from exposure and low resistance; that it would be effective as a tonic and in the treatment of debilities resulting from colds, grippe, pneumonia, catarrhal and bronchial troubles, and anemia; and that

*See also Nos. 1502, 1503, 1505, 1508, 1509, 1514, 1517, 1521, 1522, 1525, 1528-1532.

use of the product would be effective in restoring good health. The article would not be effective for such purposes.

On April 13, 1945, the Bay State Drug Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1534. Misbranding of V. M. Tablets. U. S. v. 107 Bottles of V. M. Tablets and 3,900 Circulars. Default decree of condemnation and destruction. (F. D. C. No. 15127. Sample Nos. 4201-H, 4202-H.)

On January 30, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 107 bottles of V. M. Tablets and 3,900 circulars at Philadelphia, Pa., alleging that the tablets had been shipped on or about December 6 and 29, 1944, by V. M. Products, from Chicago, Ill., and that the circulars accompanied the article when introduced into and while it was in interstate commerce.

The article was labeled in part: "V. M. A Vegetable Mucinoid Also known as Vegemucene Okra Concentrated by dehydration." The circulars were entitled "Stomach Sufferers."

Examination of samples of the article showed that it consisted essentially of mucilaginous plant material, such as okra.

It was alleged to be misbranded in that certain statements in the circulars were false and misleading since they represented and suggested that the article was effective in the treatment of gastric or peptic ulcers, duodenal ulcers, colitis, gastric hemorrhage, recurring pains, pain in the epigastrium, vomiting, loss of weight, gastritis, and cramp-like pains; that it was effective to protect the linings of the stomach and intestines from the irritant action of excess acids and food roughage; and that it would cause the user to gain weight. The article would not be effective for such purposes.

On February 20, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1535. Misbranding of Parry's Compound. U. S. v. 16 1/2 Dozen Bottles of Parry's Compound. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15295. Sample No. 10004-H.)

On February 20, 1945, the United States attorney for the Western District of Pennsylvania filed a libel against 16 1/2 dozen bottles of Parry's Compound and 100 circulars at Pittsburgh, Pa., alleging that the circulars and the drug had been shipped by the Parry Vegetable Compound Co., Inc., from Mansfield, Ohio, on or about November 1, 1944, and January 3, 1945, respectively. The circulars were entitled "Parry's Compound 'Dad' Parry's Famous Medicine 35 Years in Service."

Examination of a sample disclosed that the article consisted essentially of olive oil, water, and alcohol, colored with FD&C Red No. 2.

It was alleged to be misbranded because of false and misleading statements in the circulars which represented and suggested that the article would be effective in restoring health and in the treatment of gallstones, gallstone colic, stomach trouble, intestinal disorders, and ulcers. The article would not be effective for those purposes.

On March 20, 1945, the Parry Vegetable Compound Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1536. Misbranding of Vitalex Perdiz Tonic. U. S. v. 105 Bottles of Vitalex Perdiz Tonic. Default decree of condemnation and destruction. (F. D. C. No. 15376. Sample No. 96819-F.)

On February 13, 1945, the United States attorney for the Western District of Texas filed a libel against 105 bottles of Vitalex Perdiz Tonic at San Antonio, Tex., alleging that the article, which had been consigned by the Vitalex Laboratories, had been shipped on or about September 27, 1944, from Buffalo, N. Y.

Analysis showed that the article was a pink, sugar- and calcium carbonate-coated tablet containing nux vomica and zinc phosphide, with compounds of sodium, calcium, and iron, including phosphates. Each tablet contained iron compounds equivalent to not more than 7.1 milligrams of iron.

The article was alleged to be misbranded in that the label statements in the English and Spanish languages, "nutritional anemia, and in convalescence from

illness which has depleted the body, often resulting in loss of appetite, loss of weight, nervousness and lack of energy," were false and misleading since the article would not be efficacious in those conditions.

It was alleged to be misbranded further in that the statement on its labels, "Tonic Each tablet represents: Ext. Nux Vomica (Strychnine 0.00925 gr.) Ferric Phosphate, Insol., Sodium Glycerophosphate, Calcium Glycerophosphate, Brewer's Yeast and Zinc Phosphide," was misleading since it failed to reveal the material fact that the article was a tonic solely because of its content of nux vomica, and that it did not, when used in accordance with directions, supply a tonic dose of iron or any ingredient other than nux vomica.

On March 17, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1537. Misbranding of S-A-S Ointment. U. S. v. 9½ Dozen Jars and 5½ Dozen Jars of S-A-S Ointment. Default decree of destruction. (F. D. C. No. 14640. Sample No. 81574-F.)

On or about December 13, 1944, the United States attorney for the Western District of Missouri filed a libel against 9½ dozen 1-ounce jars and 5½ dozen 2-ounce jars of S-A-S Ointment at Kansas City, Mo., alleging that the article had been shipped on or about October 5, 1940, from Houston, Tex., by the Perl Products Co.

Examination showed that the article consisted essentially of water, soap, calcium carbonate, perfume materials, and not more than a trace of fatty material.

It was alleged to be misbranded in that the label statement, "Active Ingredients Ung. Hydrarg Ammon SP. Amon Arom Sapo Mollis Camphora Ephedrine Saponica Phenol Lanum," was false and misleading since the article did not contain ammoniated mercury, aromatic spirit of ammonia, camphor, ephedrine, phenol, or lanolin. It was alleged to be misbranded further in that certain statements on its label and in the circular enclosed with the article were false and misleading since they represented and suggested that it would be effective in the treatment of hemorrhoids, or piles, whereas it would not be effective for such purpose.

On March 6, 1945, no claimant having appeared, judgment was entered ordering that the product be destroyed.

1538. Misbranding of Si-Nif. U. S. v. 61 Bottles of Si-Nif. Default decree of condemnation and destruction. (F. D. C. No. 15262. Sample No. 23804-H.)

On February 13, 1945, the United States attorney for the Western District of Arkansas filed a libel against 61 bottles, each containing 1 fluid ounce, of Si-Nif at Texarkana, Ark., alleging that the article had been shipped on or about November 2, 1944, by the Gena Laboratories, Inc., Dallas, Tex.

Analysis showed that the article consisted essentially of glycerin and water, with small proportions of tannic acid, carbolic acid, eucalyptol, menthol, and camphor. It did not contain chlorazene.

It was alleged to be misbranded in that the label statements, "Si-Nif Recommended for Sinus Hay Fever Catarrh * * * Chlorazene," were false and misleading since the article would not be efficacious for sinus, hay fever, and catarrh, and since it did not contain chlorazene.

On March 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1539. Misbranding of Aller-Cee. U. S. v. 100 Bottles of Aller-Cee and a number of leaflets. Default decree of condemnation. Product ordered delivered to a Government hospital. (F. D. C. No. 15072. Sample No. 92866-F.)

On January 18, 1945, the United States attorney for the District of Columbia filed a libel against 100 bottles of Aller-Cee at Washington, D. C., and a number of leaflets, alleging that the drug was being offered for sale by the Vita Health Food Co. at its stores in Washington, D. C., and that the leaflets accompanied the article. It was labeled in part: "Aller-Cee * * * 100 Mgs. 2000 U. S. P. Units, each. Mfg. by Sante Vitaproducts Co. New York City."

Examination of a sample of the article indicated the presence of 104 milligrams of vitamin C per tablet.

The article was alleged to be misbranded in that the designation "Aller-Cee," on the bottle label, and certain statements and the picture of a girl sneezing, which appeared in the leaflets, entitled "Amazing Relief for Hay Fever, Asthma and Allergy Sufferers, Aller-Cee May Stop that Sneeze," were false and mis-

leading since they represented and suggested that the article would be effective in the treatment of hay fever, asthma, sneezing, and allergic conditions, whereas it would not be effective for such purposes.

On April 17, 1945, no claimant having appeared, judgment of condemnation was entered and it was ordered that a portion of the product be delivered to the Food and Drug Administration, and that the remainder be delivered for the use of a Government hospital.

1540. Misbranding of Bio-Mineral. U. S. v. 9½ Dozen Bottles and 285 Dozen Bottles of Bio-Mineral. Default decrees of condemnation and destruction. (F. D. C. Nos. 14861, 15055. Sample Nos. 75688-F, 78197-F.)

On December 27, 1944, and January 13, 1945, the United States attorneys for the District of New Jersey and the Northern District of Ohio filed libels against 9½ dozen bottles and 285 dozen bottles of Bio-Mineral at Atlantic City, N. J., and Youngstown, Ohio, respectively, alleging that the article had been shipped on or about May 25 and July 1, 1943, from Detroit, Mich., by the Bio-Mineral Products Co. The article was labeled in part: "Bio-Mineral * * * The various minerals are compounded from Ferric Chloride (Iron Chloride), Calcium Chloride, Salt (Sodium Chloride), Cobalt Chloride, Potassium Iodide, Copper Chloride, Magnesium Chloride and Manganese Chloride—all in solution in pure water. * * * Daily Portion (½ Teaspoonful Twice Daily) Contains Calcium—375.0 mgm. * * * Iodine—0.1 mgm. * * * Iron—62.0 mgm. * * * Also Sodium 117.0 mgm.; Chlorine, 1,260.0 mgm.; Magnesium, 8.0 mgm.; Copper, 2.0 mgm.; Cobalt, 1.0 mgm.; Manganese, 1.5 mgm."

Examination showed that the article possessed approximately the composition declared upon its label.

It was alleged to be misbranded in that the designation "Bio-Mineral" was false and misleading since the mineral constituents in the article would not produce or maintain life; and in that the label statements, "Supplemental Minerals to Assist in the Prevention of Nutritional Mineral Deficiencies" and "One-half Teaspoonful (2½ cc.) twice daily * * * will supply the minimum adult requirements of the essential minerals excepting Calcium," were false and misleading since the article contained no phosphorus, one of the mineral constituents essential in human nutrition and in the prevention of nutritional mineral deficiencies. The article was alleged to be misbranded further in that the following statements on the label were misleading since any combination of iron with sulfur compounds which may be present in the lower intestines would accomplish no useful purpose in the prevention of any disease condition: "Purpose of Excess Iron in the Bio-Mineral *The Iron is present in approximately six times the minimum daily adult requirement. The purpose of this excess is to supply Iron in the lower intestines (colon). This Iron, reacting with the gaseous and other obnoxious sulfur bodies, tends to render them insoluble and hence fix these bodies to prevent reabsorption in the system. (*In stating this purpose for the excess Iron present, we are attempting to explain the results so generally attained, without claiming the existence of direct scientific evidence therefor)."

On March 2 and 27, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1541. Misbranding of vitamin C tablets. U. S. v. 249 Bottles of Vitamin C Tablets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15230. Sample No. 29061-H.)

On February 12, 1945, the United States attorney for the Northern District of California filed a libel against 249 bottles of vitamin C tablets at San Francisco, Calif., alleging that the article had been shipped on or about October 9, 1944, by Oxford Products, Inc., from Cleveland, Ohio. The article was labeled in part: (Bottle) "100 C. T. Tablets Vitamin C (Ascorbic Acid) 250 Mg. Vitamin Guild Of America Cleveland, Ohio."

It was alleged to be misbranded in that the label statement, "Indication—Allergy, Hay Fever, Asthma Paroxysms, Rhinitis, Nasal Catarrh," was false and misleading since the article was not an effective treatment for the conditions named.

On April 4, 1945, the case having been removed to the Northern District of Illinois for further action, and Oxford Products, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1542. Misbranding of mineral oil. U. S. v. 999 Bottles and 33 Bottles of Penn-Champ White Oil. Default decree of condemnation and destruction. (F. D. C. No. 15073. Sample No. 73025-F.)

On January 24, 1945, the United States attorney for the Northern District of California filed a libel against 999 1-pint bottles and 33 1-quart bottles of Penn-Champ White Oil at San Francisco, Calif., alleging that the article had been shipped on or about March 23 and June 18, 1943, from Titusville, Pa., by the Penna Refining Co.

Analysis disclosed that the article was U. S. P. mineral oil.

The article was alleged to be misbranded in that the following statements on its label, "Penn-Champ White Oil is absolutely pure and harmless, and is non-fattening. It is therefore useful in 'reducing diets' and is often used in the preparation of salad dressings for general baking and frying purposes where a non-nutrient oil is desired," and "As a Substitute for Cooking Oils * * * It can be used successfully for general baking and frying purposes * * * It is also useful in the preparation of Salad Dressings as a substitute for Olive or other vegetable oils," were false and misleading because they implied that mineral oil has the properties of, and will function in the same way as, edible vegetable cooking, baking, and frying oils and is suitable for use in salad dressing, whereas mineral oil is not suitable for such uses; and since the labeling failed to reveal the material fact that mineral oil may absorb certain vitamins and minerals and prevent their assimilation by the body.

On April 2, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1543. Misbranding of Comstock's Worm Pellets. U. S. v. 141 Tins of Worm Pellets. Default decree of condemnation and destruction. (F. D. C. No. 14488. Sample No. 73261-F.)

On November 27, 1944, the United States attorney for the Northern District of California filed a libel against 141 tins of Worm Pellets at San Francisco, Calif., alleging that the article has been shipped on or about October 10, 1944, by the National New York Packing and Shipping Co., from New York, N. Y. The article was labeled in part: (Tin) "Comstock's Dead Shot Worm Pellets * * * Contains * * * Santonin"; (cap) "Active Ingredient Santonin."

Analysis showed that the article consisted essentially of sugar, cornstarch, and stearic acid, with small amounts of spigelia and methyl salicylate. No calomel or santonin was found in the article.

It was alleged to be misbranded because of the following false and misleading statements in its labeling: (Tin) "Dead Shot Worm Pellets For Round and Pin Worms This medicine helps to expel the worms Contains Active Ingredients, Calomel—Remember Worms are very Stubborn Guests in the Human Body"; (circular) "Comstock's Dead Shot Worm Pellets for Round and Pin Worms if you are Not Sure that All the Worms and their Eggs have been Removed. The same Dose should be Taken Two Weeks after the First Dose."

On March 3, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

1544. Misbranding of Midwest Hi-Culture Vi-Tonic. U. S. v. 10 Bags of Midwest Hi-Culture Vi-Tonic. Default decree of condemnation and destruction. (F. D. C. No. 15051. Sample No. 68456-F.)

On January 11, 1945, the United States attorney for the Northern District of Ohio filed a libel against 10 bags, each containing 100 pounds, of the above-named product at Rudolph, Ohio, alleging that the article had been shipped on or about May 22, 1944, by the Midwest Mineral Co., Indianapolis, Ind.

Analysis showed that the article consisted essentially of mineral and plant material, including charcoal, sulfur, salt, and compounds of calcium, phosphorus, and iodine.

The article was alleged to be misbranded in that certain statements in an accompanying circular entitled "Directions For Culturing With Hi-Culture Vi-Tonic" were false and misleading since they represented and suggested that use of the article as a feed supplement would lower hog production costs and would enable the user to raise strong healthy pigs and produce pork quickly and inexpensively; and that the article would be effective in the prevention and treatment of negro and other pig troubles, intestinal putrefaction, toxic poison conditions, and necrotic enteritis and other nutritional diseases, whereas the article would not be effective to produce such results.

On February 10, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1545. Misbranding of Rex Wheat Germ Oil. U. S. v. 3 Deals and 4 Bottles of Rex Wheat Germ Oil. Default decree of condemnation and destruction. (F. D. C. No. 14648. Sample No. 87389-F.)

On December 15, 1944, the United States attorney for the Northern District of Iowa filed a libel against 3 deals and 4 1-gallon bottles of the above-named product at Cedar Rapids, Iowa, alleging that the article had been shipped on or about July 26 and September 22, 1944, by the Globe Laboratories, from Fort Worth, Tex. The article was labeled in part: "Rex Wheat Germ Oil * * * Vio Bin Corporation, Monticello, Illinois."

Each of the deals consisted of a carton containing 2 1-quart bottles, 4 1-pint bottles, and 3 4-ounce bottles, together with a manila envelope bearing the notation "To the Manager," which envelope contained various pieces of printed matter discussing the alleged virtues of the article. Examination showed that the article contained a dark brown, oily liquid identical in appearance to wheat germ oil.

The article was alleged to be misbranded in that certain statements on the bottle labels, on the manila envelope, and in the printed matter enclosed in the envelope, were false and misleading since they represented and suggested that the article would be effective in preventing or correcting breeding difficulties in cattle, pigs, sheep, poultry, dogs, and other animals; that it would be effective to produce a healthy coat and skin in dogs, and cure summer eczema in dogs; that use of the article would increase the livability of young dogs, keep the dog's coat glossy, soft, and free of dandruff and scale, promote growth of hair and contribute to a dog's general health; that it would be effective in the treatment of itchy, sore, or scaly skin; that it would increase the fertility of hens and the hatchability of eggs; and that it was effective in treating abortion and simple sterility in cows, in bringing calves through to full term in cows with Bang's disease, in treating barrenness in sows, in causing mares to breed, and in producing thriffter livestock, whereas the article would not be effective for the purposes claimed.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On February 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product, together with the envelope and printed matter, was ordered destroyed.

1546. Misbranding of L. T. Barrick's Compound Mixture. U. S. v. 249 Bottles of L. T. Barrick's Compound Mixture. Default decree of condemnation and destruction. (F. D. C. No. 15068. Sample No. 87839-F.)

On January 23, 1945, the United States attorney for the Northern District of Iowa filed a libel against 249 bottles, each containing 4 fluid ounces, of the above-named product at Arlington, Iowa, alleging that the article had been shipped on or about October 13, 1944, by L. T. Barrick, from Byron, Ill.

Examination of a sample showed that the article consisted essentially of water, bismuth subnitrate, 4.4 grains per teaspoonful; calcium carbonate, 3.1 grains per teaspoonful; resorcin, camphor, and benzoic acid, 0.2 grain per teaspoonful; catechu; and alcohol, 14.6 percent.

The article was alleged to be misbranded in that certain statements on its labels and in the circular entitled "Special Directions," enclosed in the retail carton, were false and misleading since they represented and suggested that it was effective in the treatment of scours in calves and pigs, and that it contained 20 percent of alcohol, whereas it was not effective for such purpose, and it did not contain 20 percent of alcohol.

On February 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1547. Misbranding of Chezit. U. S. v. 168 Packages and 165 Packages of Chezit. Default decree of condemnation and destruction. (F. D. C. No. 15116. Sample No. 87599-F.)

On January 29, 1945, the United States attorney for the Northern District of Iowa filed a libel against 168 1-pound packages and 165 8-ounce packages of Chezit at Spencer, Iowa, alleging that the article had been shipped on or about November 24, 1944, from Chicago, Ill., by the United Farmers Exchange.

Examination showed that the article consisted of calcium carbonate, 50 percent; zinc sulfocarbolate, 2.6 percent; bismuth subcarbonate, 0.32 percent; plant material, including nux vomica; and potassium iodide.

The article was alleged to be misbranded in that the statements on its label which represented and suggested that it was of value in checking diarrhea, scours, and looseness of the bowels in livestock, and in relieving bowel irritation;

were false and misleading since the article was of no value in checking those conditions in livestock or in furnishing relief from any irritation of the digestive tract. The article was alleged to be misbranded further in that its container (1-pound size) was so filled as to be misleading since the contents occupied only about 57 percent of the volume of the container.

On February 27, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1548. Misbranding of Franklin Gi-Co, Franklin Udder-Eze, and Franklin N-C-K Compound. U. S. v. 20 Bottles of Franklin Gi-Co, 51 Jars of Franklin Udder-Eze, 21 Boxes of Franklin N-C-K Compound, and 30 booklets. Default decree of destruction. (F. D. C. No. 14879. Sample Nos. 69981-F, 69982-F, 69984-F.)

On January 12, 1945, the United States attorney for the District of Utah filed a libel against 20 bottles of Franklin Gi-Co, 51 jars of Franklin Udder-Eze, 21 boxes of Franklin N-C-K Compound, and 30 booklets entitled "Franklin Vaccines and Supplies Catalog No. 44" at Salt Lake City, Utah, alleging that the O. M. Franklin Serum Co. had shipped the articles from Denver, Colo., between the approximate dates of October 9 and November 7, 1944, and the booklets on or about October 11, 1944, and that the booklets accompanied the articles when they were introduced into and while they were in interstate commerce.

Examination of a sample of the Franklin Gi-Co showed that it was essentially a mixture containing alcohol, cresol, and an emulsifying agent, and volatile oils including oil of eucalyptus. The article was alleged to be misbranded in that the statements in the accompanying booklet, "For use in the treatment of certain infections of the respiratory and intestinal tract of horses, cattle, sheep, swine and poultry. Especially effective when used in drinking water for poultry, or in a mash or slop feed. * * * for herd or flock treatment. * * * when given internally is absorbed by the mucous membrane of the intestines and eliminated through the respiratory tract and kidneys," were false and misleading since the article would not be effective in the treatment of respiratory diseases of poultry or other animals.

Examination of a sample of the Franklin Udder Eze showed that it was essentially a mixture of petrolatum, lanolin, methyl salicylate, creosote, and salicylic acid. The article was alleged to be misbranded in that the statements in the accompanying booklet, "For treatment of inflammatory conditions of the udder in cows, mares, ewes and sows. In treating cows, best results are obtained by using in conjunction with Bovine Mixed Bacterin Formula 2. * * * Apply ointment at least twice daily, massaging the affected parts thoroughly at each application. Massaging will assist in * * * reducing inflammation. In severe cases, * * * the ointment will prove very beneficial. * * * for eczema and for sprains, bruises, rheumatic swellings, throat inflammation," were false and misleading since the article would not be effective in the treatment of the conditions mentioned.

Examination of a sample of the Franklin N-C-K Compound showed that it was essentially a mixture including copper sulfate, nicotine, saponifiable oil, and ground soy bean. The article was alleged to be misbranded in that the statements in the accompanying booklet, "A popular and easily administered toner or conditioner. * * * Animals put on weight while being treated and increased appetite will be noted following treatment," were false and misleading since the article would not be effective to fulfill the promises of benefit stated and implied by those statements.

On March 10, 1945, no claimant having appeared, judgment was entered ordering that the product, including the booklets, be destroyed.

1549. Misbranding of Star Sulphur Compound. U. S. v. 13½ Dozen Bottles and 21½ Dozen Bottles of Star Sulphur Compound, and 198 leaflets. Default decree of condemnation and destruction. (F. D. C. No. 15750. Sample Nos. 23909-H, 23918-H.)

On March 27, 1945, the United States attorney for the Northern District of Alabama filed a libel against 13½ dozen 6-ounce bottles and 21½ dozen 2-ounce bottles of Star Sulphur Compound, and 198 leaflets entitled "Star Sulphurous Compound Poultry Raising Made Easy," at Birmingham, Ala., alleging that the article and the leaflets had been shipped on or about October 17, 1944, by the Star Chemical Co., Arlington, Tex.

Examination showed that the article consisted of a lime and sulfur solution.

The article was alleged to be misbranded in that certain statements in the leaflets were false and misleading since they represented and suggested that the article was effective in ridding the intestines of poultry of germs and worms,

and was effective in exterminating lice-mites, fleas, and blue bugs on poultry, whereas the article was not effective for such purposes. The article was alleged to be misbranded further in that the label statement, "Active Ingredients * * * Calcium Polysulphide, Calcium Thio-Sulphate, Sulphur," was false and misleading since the ingredients named were not active when the article was used as directed.

On April 27, 1945, no claimant having appeared, judgment of condemnation was entered and the product and the leaflets were ordered destroyed.

1550. Misbranding of Poul-Tra-Tone. U. S. v. 54 Bottles, 24 Jugs, and 11 Jugs of Poul-Tra-Tone, including all labeling. Default decree of destruction. (F. D. C. No. 15278. Sample No. 18317-H.)

On February 21, 1945, the United States attorney for the District of Minnesota filed a libel against 54 quart bottles, 24 half-gallon jugs, and 11 gallon jugs of Poul-Tra-Tone at Arlington, Minn., and against all labeling of the article of drug consisting of a supply of circulars at Arlington, Minn., entitled: "20 Suggestions for Making Chick Raising Easier and Better." It was alleged that the Dutton Co. had shipped the article of drug from Galesville, Wis., on or about March 27 and June 27, 1944, and the circulars from that place on or about February 15, 1944.

Analysis showed that the drug was an aqueous solution containing, essentially, potassium dichromate, potassium nitrate, magnesium sulfate, and a small amount of chlorate.

The article was alleged to be misbranded in that the statements on its label and in the circulars were false and misleading since they represented and implied that it would be effective for the prevention and treatment of coccidiosis, anemic conditions, worms, surplus mucus, simple diarrhea, and other disease conditions of poultry involving the intestinal tract, whereas the product, when used as directed on the label, would be practically worthless and would have no value for such disease conditions.

On April 5, 1945, no claimant having appeared, judgment was entered ordering the destruction of the product.

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PRODUCTS

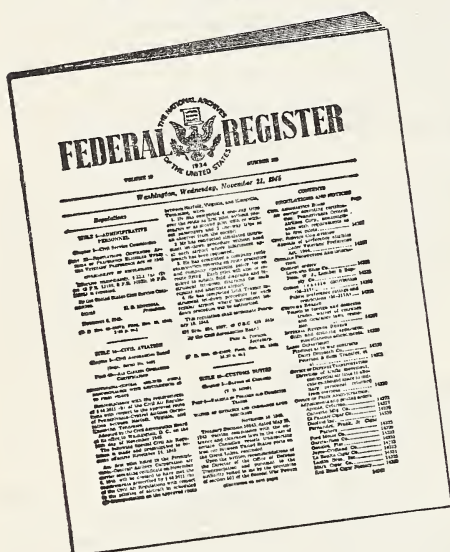
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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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Belmont Co.:		Oxford Products, Inc.:	
Burma Foot Cream-----	1505	vitamin C tablets-----	1541
Berg Sales Co.:		Parry Vegetable Compound Co., Inc.:	
prophylactics-----	1527	Parry's Compound-----	1535
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Bio-Mineral-----	1540	mineral oil-----	1542
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Medical Supply Co.:		prophylactics-----	1531
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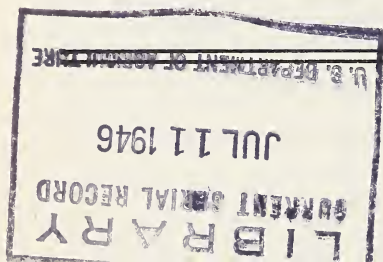
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1551-1600

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., May 21, 1946.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1551. Action to restrain interstate shipment of Bullock's System Self-Treatment for Sinus and Catarrhal Infection. U. S. v. Bullock's Laboratories, Inc., Henry Spangler, Dr. Thomas J. Howerton, Theodore T. Golden, and G. M. Koutz. Permanent injunction granted. (Inj. No. 85.)

COMPLAINT FILED: March 5, 1945, Eastern District of Virginia, against Bullock's Laboratories, Inc., Alexandria, Va., and Henry Spangler, principal agent of the corporation, Dr. Thomas J. Howerton, president, Theodore T. Golden, secretary-treasurer, and G. M. Koutz, vice president of the corporation.

NATURE OF CHARGE: Since February 24, 1944, the defendants had been preparing, packing, and distributing in interstate commerce a misbranded product known as *Bullock's System Self-Treatment for Sinus and Catarrhal Infection*, which consisted of drugs labeled "Bullock's Emollient," "Bullock's Nasal Salve," "Ear Oil," "Bullock's A. H. C." (formerly known as "Bullock's Antiseptic Healing and Cleansing Tonic"), and "KCK An Alkaline Combination" (formerly known as "King Cold Knockout"), and a device consisting of a douche or irrigation can, rubber tubing, and nasal tip, together with a nasal atomizer, a thermometer, and a measuring cup. The drugs had essentially the same

*For failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, see Nos. 1555, 1556, 1558, 1577, 1600; failure to bear an accurate statement of the quantity of the contents, Nos. 1553, 1555, 1556, 1558, 1577, 1592, 1599, 1600; failure to bear in the English language the information required by Section 502 (f) (1), No. 1553; omission of, or unsatisfactory, ingredients statements, Nos. 1553, 1555-1557, 1559-1561, 1564-1566, 1585, 1599, 1600; product requiring certificate or release, for which none had been issued, No. 1554; no new-drug application effective, No. 1557; substitution of a drug and its sale under the name of another drug, Nos. 1571, 1586, 1587; deceptive packaging, Nos. 1581, 1586, 1587, 1594; imitation of another drug, Nos. 1586, 1587; giving of a false guaranty, No. 1571; cosmetics, actionable under the drug provisions of the Act, Nos. 1592-1594.

composition as those of similar articles involved in the case reported in notices of judgment on drugs and devices, No. 908.

The *System* was alleged to be misbranded in the following manner: Section 502 (a), certain statements in the labeling, including those in accompanying booklets entitled "Directions for Use of Bullock's System" and "Fight Infection with Bullock's System," and in an accompanying folder entitled "Infectious Catarrh Symptoms," were false and misleading since they represented and suggested that the *System* would constitute an effective treatment for acute or chronic sinus trouble, hay fever, nasal catarrh, nasal ailments, infectious catarrh, abscesses and infected teeth, throat and tonsil infections, bronchitis, mastoid trouble, asthma, colitis, ulcers and catarrh of the stomach, tumors, rheumatism, arthritis, blindness, and deafness. The *System* did not constitute an effective treatment for the conditions named. Further misbranding, Section 502 (j), the *System* would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling since it was intended for use in the irrigation of the nasal passages, whereas such irrigation is always accompanied by danger to the health of users by loosening the infected material from the nasal walls and spreading the infection to the opposite nasal passage, to the nasal sinuses, or to the ears.

It was also alleged in the complaint that, previous to the incorporation of Bullock's Laboratories, Inc., the business of preparing and distributing the *System* had been carried on by Henry Spangler as an individual trading under the name of National Laboratories, Inc.; that, while so operating, criminal proceedings had been instituted against Henry Spangler (as reported in notices of judgment on drugs and devices, No. 908), resulting in a sentence of 180 days in jail, which sentence was suspended on condition that he was not then selling and would not again engage in the sale of the *System*; and that, thereafter, Henry Spangler was instrumental in securing, for the purpose of preparing and distributing the *System*, the formation of the corporation known as Bullock's Laboratories, Inc.

PRAYER OF COMPLAINT: That a preliminary injunction issue, restraining the defendants from commission of the acts complained of; and that, after due proceedings, the preliminary injunction be made permanent.

DISPOSITION: On March 13, 1945, the corporation and Theodore T. Golden and Henry Spangler having entered their appearances, and the other defendants having failed to appear, a preliminary injunction was entered, restraining all defendants from shipping any misbranded drugs and devices, and particularly the so-called "Bullock's System," in interstate commerce for the period ending on April 16, 1945. On the latter date, the defendants having failed to answer or otherwise plead to the complaint, a decree was entered directing that the preliminary injunction be made permanent.

1552. Adulteration and misbranding of Interferin. U. S. v. Don C. Keefer (Keefer Laboratories). Plea of nolo contendere. Sentence of 1 year in jail. (F. D. C. No. 7241. Sample Nos. 14766-E, 86683-E.)

INFORMATION FILED: October 25, 1944, Northern District of Illinois, against Don C. Keefer, trading as the Keefer Laboratories, Chicago, Ill.

ALLEGED SHIPMENT: On or about November 3, 1941, and March 19, 1942, from the State of Illinois into the States of Pennsylvania and Wisconsin.

NATURE OF CHARGE: Adulteration (shipment of November 3, 1941), Section 501 (c), the purity of the article fell below that which it purported and was represented to possess. It purported and was represented to be sterile by reason of the fact that it was recommended in the labeling for injection into the cervix and pregnant uterus under conditions of the strictest asepsis, whereas it was not sterile but was contaminated with viable pathogenic micro-organisms.

Misbranding (same shipment), Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling; and, Section 502 (a), the labeling was false and misleading since it represented and suggested that the article, when used by or on the prescription of a physician, was a safe and appropriate medicament for use in effecting abortion, whereas, when used by or on the prescription of a physician, or otherwise, it was not a safe and appropriate medicament for use in effecting abortion, but was unsafe and dangerous, and capable of producing serious and even fatal consequences; and the label statements, "The placenta is usually expelled a few minutes after the fetus," "Severe hemorrhages are very rarely observed after the use of Interferin,"

and "the Interferin method is positively superior to dilation and curettage in cases of gravidity from two and a half to six months," were false and misleading since, in cases of abortion induced by the use of the article, the placenta would not usually be expelled a few minutes after the fetus, severe hemorrhages would not be rarely observed after the use of the article, but would frequently occur after such use, and the results obtained by the use of the article in cases of gravidity from 2½ to 6 months would not be superior to those obtained by dilation and curettage.

Misbranding (shipment of March 19, 1942), Section 502 (a), the labeling statements, "Caution: For use by Licensed Physician only. * * * Indications: Amenorrhea, Dysmenorrhea, Endocervicitis, Endometritis, Spontaneous, Incomplete, Threatened Abortion," were false and misleading since they represented and suggested that the article, when used by a licensed physician, was a safe and appropriate medicament for use in the treatment of spontaneous, incomplete, and threatened abortion, and that it was a safe and appropriate treatment for amenorrhea, dysmenorrhea, endocervicitis, and endometritis. The article, whether used by a licensed physician or otherwise, was not a safe and appropriate medicament for the treatment of such conditions, but was unsafe and dangerous, and capable of producing serious and even fatal consequences.

DISPOSITION: June 21, 1945. A plea of nolo contendere having been entered by the defendant, the court imposed a sentence of 1 year in jail, to run concurrently with the sentence imposed in the case reported in notices of judgment on drugs and devices, No. 1558.

1553. Misbranding of Stanley's Stomach Powder, Prescription 1-NN-1 Nerve Tablets, Prescription 1-RR-7, External No. 1, Prescription 1-H-7, and Prescription Medicine 1-B-7. U. S. v. Sophia Strboya Sikoparija (Stanley's Drug Store). Plea of not guilty. Tried to the jury; verdict of guilty. Sentence of 57 days in jail. (F. D. C. No. 11379. Sample Nos. 14838-F, 14839-F, 15010-F, 15011-F, 38339-F, 38340-F.)

INFORMATION FILED: May 8, 1944, Eastern District of Texas, against Sophia Strboya Sikoparija, trading as Stanley's Drug Store, Orange, Tex.

ALLEGED SHIPMENT: Between the approximate dates of January 21 and February 20, 1943, from the State of Texas into the States of Wisconsin and California.

PRODUCT: Analyses disclosed that the *Stanley's Stomach Powder* consisted essentially of sodium bicarbonate and Rochelle salt, flavored with anise oil; that the *Prescription 1-NN-1 Nerve Tablets*, the *Prescription 1-RR-7*, and the *Prescription Medicine 1-B-7* contained ½ grain of phenobarbital per tablet; that the *External No. 1* consisted essentially of basic aluminum acetate and sodium acetate; and that the *Prescription 1-H-7* consisted essentially of extracts of plant drugs, including a laxative drug such as senna, sugar, alcohol, and water.

NATURE OF CHARGE: *Stomach Powder*, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be beneficial in the treatment of stomach disorders; that it would be efficacious in the cure, mitigation, treatment, or prevention of stomach pain due to gas, nausea, and heaviness after meals; and that it would be efficacious to correct indigestion, strengthen the digestive organs, and soothe and heal stomach tissues, whereas it would not be efficacious for such purposes; Section 502 (b) (2), the label bore no statement of the quantity of the contents; and, Section 502 (e) (2), the label did not bear the common or usual names of the active ingredients of the article.

Prescription 1-NN-1 Nerve Tablets, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of nervousness, restlessness, sleeplessness, worry or excitement, depressed spirits, and nervous headaches, whereas the article would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital, a derivative of the narcotic or hypnotic substance barbituric acid, which derivative has been found to be and by regulations designated as habit forming, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502 (j), the article consisted of tablets, each containing approximately ½ grain of phenobarbital, and it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, "Direction: Adults: Take 1 Tablet three times a

day with full glass of water"; and, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents.

Prescription 1-RR-7, misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of high blood pressure, headaches, heat and fullness of the head, heat and redness of the face, dizziness, noise in the ears, sleeplessness at night, and oppressed breathing due to rush of blood to the head, whereas the article would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital and its label failed to bear the required warning; Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the article bore no directions for use.

External No. 1, misbranding, Section 502 (a), the label statement, "cover the sore," was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, or treatment of sores, whereas it would not be efficacious for such purposes; Section 502 (b) (2) the label of the article bore no statement of the quantity of the contents; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient of the article.

Prescription 1-H-7, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the treatment of liver ailments; that it would be efficacious in the cure, mitigation, treatment, or prevention of disordered conditions of the liver, stomach, and bowels; and that it would have a tonic effect upon the large intestine, whereas the article would not be efficacious for such purposes; Section 502 (e) (2), the label failed to bear the common or usual names of the active ingredients of the article; and, Section 502 (f) (2), the article was a laxative and its label failed to warn that it should not be taken when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and its labeling also failed to warn that frequent or continued use of the article might result in dependence upon a laxative to move the bowels.

Prescription Medicine 1-B-7, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of nervousness, sleeplessness, worry, and weak nerves, whereas it would not be efficacious for such purposes; Section 502 (d), the article contained phenobarbital and its label failed to bear the required warning; Section 502 (j), the article would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, (translation from Slovenian) "Directions: 1 portion 3 times a day before meals with half a cup of lukewarm water. Later it suffices to use 1 or 2 a day"; and, Section 502 (c), adequate directions for use required by Section 502 (f) (1) did not appear on the label in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase or use, since that information was not in the English language.

The information also alleged that another article, *Hair Milk*, was misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

DISPOSITION: A plea of not guilty having been entered on behalf of the defendant the case came on for trial before a jury on October 24, 1944. The jury returned a verdict of guilty, and on October 25, 1944, the court sentenced the defendant to serve 57 days in jail.

1554. Misbranding of Dimels Capsules and Aditis Capsules. U. S. v. Jones-Hague, Inc., and Carlos W. Jones. Pleas of not guilty. Tried to the court and jury; verdict of guilty. Motion for new trial denied. Fine, \$100 and costs. (F. D. C. No. 10590. Sample Nos. 2557-F, 3345-F, 3809-F.)

INFORMATION FILED: December 31, 1943, Western District of Pennsylvania, against Jones-Hague, Inc., a corporation, and Carlos W. Jones, president and treasurer, McKeesport, Pa.

ALLEGED SHIPMENT: On or about July 15, 1942, and March 11 and April 8, 1943, from the State of Pennsylvania into the State of Missouri.

LABEL, IN PART: "Dimels * * * Contains Hormone Complexes as found in Isles Langerhans," and "Aditis * * * Contains Strychnine Sulphate. $\frac{1}{200}$ gr. * * * Thyroid Glands U. S. P. 1 Gr. * * * Barium Iodide $\frac{1}{10}$ gr. Leptandrin $\frac{1}{8}$ gr. Vehicle q. s."

NATURE OF CHARGE: *Dimels Capsules*, misbranding, Section 502 (k), the article was composed in whole or in part of insulin which was not from a batch for which a certificate or release had been issued pursuant to Section 506; Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that, when consumed according to the directions in the labeling, the article would not produce the effect of the hormones found in the Islands of Langerhans, which fact was material in view of the following representations on the labels: "Each capsule Contains Hormone Complexes as found in Isles Langerhans * * * Dosage—One capsule three times daily."

Further misbranding, Section 502 (a), the statements on the labels, "To be taken only upon advice of a physician. Its use otherwise may be dangerous. To be used only in uncomplicated and incipient diabetes," were false and misleading since they represented and suggested that the article, when taken as directed, would be physiologically active and would be dangerous unless taken upon the advice of a physician, and that, when taken as directed, it would be of value in the treatment of uncomplicated and incipient diabetes. The article, when taken as directed, was inert and physiologically inactive, and whether taken upon the advice of a physician or otherwise, it would not be dangerous and it would not be of value in the treatment of uncomplicated and incipient diabetes.

Aditis Capsules, misbranding, Section 502 (j), the article contained barium iodide and thyroid in amounts which would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the following directions from the labeling: "Dose—One to three capsules daily."

DISPOSITION: On May 23 and 24, 1944, the case was tried to a jury and a verdict of guilty was returned with respect to both defendants on all counts. On May 29, 1944, a motion for a new trial was filed on behalf of the defendants, which motion was denied on June 19, 1945. On June 28, 1945, the court imposed a fine of \$100 and costs.

1555. Misbranding of Lax Thyroid Tablets. U. S. v. Edward S. Hidden (Carolina Chemical Co.). Plea of guilty. Fine, \$500. Sentence of 1 year imprisonment suspended; defendant placed on probation for 5 years, conditioned upon payment of fine. (F. D. C. No. 14262. Sample Nos. 68126-F, 68501-F.)

INFORMATION FILED: February 6, 1945, Eastern District of South Carolina, against Edward S. Hidden, trading as the Carolina Chemical Co., Charleston, S. C.

ALLEGED SHIPMENT: On or about May 20 and June 30, 1944, from the State of South Carolina into the State of Ohio.

PRODUCT: The *Lax Thyroid Tablets* consisted of white and pink tablets in one shipment and light-colored and pink tablets in the other shipment. The tablets were packaged in envelopes in which were enclosed certain mimeographed sheets entitled "Lax Thyroid Tablets."

Analyses showed that each of the white and light-colored tablets contained approximately $\frac{1}{2}$ grain of thyroid, and that each of the pink tablets contained plant drugs, including the laxative drug aloin.

NATURE OF CHARGE: White and light-colored tablets, misbranding, Section 502 (j), the tablets, by reason of the fact that each contained approximately $\frac{1}{2}$ grain of thyroid, would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: (Envelopes containing the light-colored tablets) "Thyroid Tablets * * * Directions: One tablet at bedtime or one tablet before meals"; (mimeographed sheets accompanying the white and light-colored tablets) "Take one Lax Thyroid Tablet at bedtime. If you want to increase dosage you may take one before each meal. * * * Lax Thyroid Tablets are intended to be used as a week-by-week treatment. Do not expect extraordinary results from taking one packing. * * * Loss of weight with Lax Thyroid Tablets does not usually start at once. It may take a few days or even a few weeks to get things started in the right direction. * * * It takes a little time to experience the benefits of this treatment." Further misbranding, Section 502 (a), certain statements in the mimeographed sheets were false and misleading since they represented and created the impression that the tablets would be a safe and appropriate remedy for the treatment of obesity,

and that the use of the tablets would result in greater vitality and a general feeling of well-being in the user. The article would not be a safe and appropriate remedy for obesity, but was a dangerous drug, and its use would not result in greater vitality and a general feeling of well-being in the user.

All tablets, misbranding, Section 502 (b) (1), the labels on the envelopes containing the tablets bore no statement containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the labels bore no statement of the quantity of the contents of the envelopes; and, Section 502 (e) (2), the labels of the tablets failed to bear the common or usual name of each active ingredient, and, in the case of the light-colored tablets, the label failed to bear the name of one of the ingredients, thyroid, and the quantity or proportion of thyroid contained in the tablets.

The information also alleged that an article known as *Vitalex Tablets* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 18, 1945. A plea of guilty having been entered, the court imposed a fine of \$500 covering both violations, and sentenced the defendant to imprisonment for 1 year. The jail sentence was suspended and the defendant was placed on probation for 5 years, conditioned upon the payment of the fine.

1556. Misbranding of N. M. Tablets, C. C. Pills, and N. K. Tablets. U. S. v. Maxwell Zedd (Zedd's Cut Rate Drug Stores). Plea of nolo contendere. Fine, \$150. (F. D. C. No. 14236. Sample Nos. 53242-F, 53277-F, 53278-F.)

INFORMATION FILED: May 8, 1945, Eastern District of Virginia, against Maxwell Zedd, trading as Zedd's Cut Rate Drug Stores, at Norfolk, Va.; charging that the defendant, while holding the tablets and pills for sale after shipment in interstate commerce, had removed, on or about November 23, 1943, and February 10, 1944, a number of the tablets and pills from the containers in which they had been shipped and had repacked them into boxes and envelopes labeled as hereinafter described, which acts of removal and repacking resulted in the misbranding of the articles.

PRODUCT: Analyses disclosed that the *N. M. Tablets* consisted essentially of extracts of damiana and nux vomica, zinc phosphide, and starch, coated with calcium carbonate and sugar, and colored red; that the *C. C. Pills* contained calomel, compound extract of colocynth, resin of jalap, and gamboge; and that the *N. K. Tablets* consisted of approximately 1 grain of methylene blue, cubeb, santal oil, and possibly other extractives.

LABEL IN PART: (Envelopes) "C. C. Pills 10¢"; (boxes) "N. M. [or "N. K."] Tablets One three times a day Zedd's Cut Rate Drug Stores * * * Norfolk, Va."

NATURE OF CHARGE: *N. M. Tablets*, misbranding, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, by reason of the presence of zinc phosphide, nux vomica, and cantharides; Section 502 (b) (2), its label bore no statement of the quantity of the contents; and, Section 502 (e), its label failed to bear the common or usual name of each active ingredient, including the name and quantity or proportion of any strychnine.

C. C. Pills, misbranding, Section 502 (b) (1) (2), the envelopes containing the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e), the label failed to bear the common or usual name of each active ingredient, including the name and proportion of calomel, a derivative of mercury; Section 502 (f) (1), the envelopes bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the article (a laxative) bore no warnings against use in those pathological conditions, or by children, where its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

N. K. Tablets, misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e), the label did not bear the common or usual name of each active ingredient; Section 502 (f) (2), the article, by reason of the presence of methylene blue, santal oil, and cubeb, should have borne, but failed to bear, a label warning that its use should be discontinued if disturbance of the stomach or bowels, or skin rashes, were noticed, which warning was necessary for the protection of users.

DISPOSITION: May 17, 1945. A plea of *nolo contendere* having been entered, the court imposed a fine of \$50 on each of 3 counts, a total fine of \$150.

1557. Misbranding of Yuk-Air Compound. U. S. v. 239 Bottles and 198 Bottles of Yuk-Air Compound, and a quantity of printed matter. Default decrees of condemnation and destruction. (F. D. C. Nos. 11939, 12025. Sample Nos. 49064-F, 59721-F.)

LIBELS FILED: March 10 and 23, 1944, Southern District of Indiana and Western District of Michigan.

ALLEGED SHIPMENT: By the Universal Drug Products, Inc., from Cleveland, Ohio. A portion of the product and printed matter was shipped on or about February 8, 1944, and the remainder of the product and part of the printed matter were shipped on or about February 18, 1944, with the remainder of the printed matter being shipped on or about February 21, 1944.

PRODUCT: 239 various-sized bottles of *Yuk-Air Compound* and 2,000 circulars entitled "Yuk-Air Daily," at Indianapolis, Ind.; and 198 various-sized bottles of the same product and 150 circulars of the same title, together with one placard imprinted "Laboratory Lecture Genuine Australian Eucalyptus Oil Yuk-Air No Colds All Winter" and 3 placards entitled "Genuine Australian Eucalyptus Oil," at Muskegon, Mich. Analysis showed that a portion of the product was a yellow liquid containing Eucalyptus and turpentine oils, while the remainder of the product consisted of a clear, colorless liquid containing, essentially, turpentine oil.

NATURE OF CHARGE: Section 505, the article was a new drug which should not have been introduced into interstate commerce since no application filed pursuant to Section 505 of the law was effective with respect to the article.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage suggested in the statements in the labeling, "Eucalyptus Oil * * * used in * * * ear oils," and "It may be used safely on any part of the body," since, when used in the ears, the article would cause injury; Section 502 (f) (1), the labeling of a portion of the article did not bear adequate directions for use in all conditions for which use of the article was suggested in its labeling and as interpreted by representations orally made on behalf of the manufacturer, namely, for application into the ears; Section 502 (f) (2), the labeling bore no warnings against allowing the article to get into the eyes, ears, or onto the mucous membrane, nor against continued use of the article if excessive irritation developed, which warnings are necessary for the protection of users of products containing turpentine; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each ingredient since the designation "Oil of Pinene," borne on the label, is not the common or usual name of spirits of turpentine.

Further misbranding, Section 502 (a), certain statements in the labeling were false and misleading since the article would not be safe for use on every part of the body; it could not be used and rubbed on freely without fear of irritation of any kind; it was not an efficacious treatment for stiff joints and sore muscles due to exposure; it was not appropriate for use generally as a massaging or rubbing oil, as represented and suggested by the labeling; and the article was not Australian oil or Eucalyptus oil, as was implied, but was composed largely of turpentine oil produced domestically.

DISPOSITION: May 1 and 5, 1944. No claimant having appeared, judgments of condemnation were entered and the product and printed matter were ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1558. Misbranding of Interferin. Two indictments: U. S. v. Don Keefer. Pleas of not guilty. Tried to the court; verdict of guilty. Sentences of 1 year in jail on each indictment. (F. D. C. Nos. 17800, 17801. Sample Nos. 17228-H, 20045-H.)

INDICTMENTS RETURNED: May 11, 1945, Northern District of Illinois, against Don Keefer, Chicago, Ill.

ALLEGED SHIPMENT: On or about November 27, 1944, and April 6, 1945, from the State of Illinois into the States of Indiana and Nebraska.

*See also Nos. 1553, 1556, 1557.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the article did not bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it did not bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and, Section 502 (f) (1), the article did not bear a label containing adequate directions for use.

DISPOSITION: June 21, 1945. Pleas of not guilty having been entered by the defendant, the cases came on for trial before the court, at the conclusion of which the defendant was found guilty and was sentenced to 1 year in jail on each indictment, the sentences to run concurrently with each other and with the sentence imposed in the case reported in notices of judgment on drugs and devices, No. 1552.

1559. Misbranding of Prescription 1-H-7, Tonic 1-X-1, Red Blood Purifier, and Prescription 1-VV-1. U. S. v. Sophia Strboya Sikoparija (Stanley's Drug Store). Plea of not guilty. Tried to a jury; verdict of guilty. Sentence of 6 months in jail suspended and defendant placed on probation for 5 years. (F. D. C. No. 12592. Sample Nos. 40450-F, 40451-F, 75362-F, 78664-F, 78665-F.)

INFORMATION FILED: October 17, 1944, Eastern District of Texas, against Sophia Strboya Sikoparija, trading as Stanley's Drug Store, Orange, Tex.

ALLEGED SHIPMENT: Between the approximate dates of January 5 and May 6, 1944, from the State of Texas into the States of Wisconsin, Pennsylvania, and Indiana.

PRODUCT: Analyses disclosed that the *Prescription 1-H-7* consisted essentially of extracts of plant drugs including laxative drugs and an alkaloid-bearing drug, sugar, alcohol, and water; that the *Tonic 1-X-1* consisted essentially of extracts of plant drugs including an alkaloid-bearing drug, sugar, alcohol, and water; that the *Red Blood Purifier* consisted essentially of a small proportion of potassium iodide and water, flavored with peppermint; and that the *Prescription 1-VV-1* consisted of sodium bicarbonate flavored with anise.

NATURE OF CHARGE: *Prescription 1-H-7*, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of headaches and dizziness, and that it possessed properties which would have a tonic effect upon the intestines, whereas the article would not be efficacious for the purposes claimed and did not possess the properties represented; Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient of the article; and, Section 502 (f) (2), the article was a laxative, and its labeling failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and it also failed to warn that frequent or continued use of the article might result in dependence on laxatives to move the bowels.

Tonic 1-X-1, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious as a tonic in run-down, pale, and weak conditions; that it was a strengthening tonic and stimulant; that it would be efficacious in the cure, mitigation, treatment, and prevention of nervous debility, exhausted and depressed conditions, and weakness; and that it would be of value to convalescent and aged persons. The article would not be efficacious for the purposes represented.

Red Blood Purifier, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in purifying the blood, and that it would be beneficial to persons afflicted with pimples, boils, skin eruptions, and liver spots, whereas the article would not be efficacious for such purposes; Section 502 (e) (2), the article failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the article contained potassium iodide, and its labeling failed to warn that it should not be used in cases of lung disease, chronic coughs, or goiter (thyroid disease), except upon the advice of a physician, and it also failed to warn that use of the article should be discontinued if a skin rash appeared.

Prescription 1-VV-1, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of chest colds, coughs, croup, influenza, grippe, flu, pain in the chest, difficult breathing, short, oppressed breathing, stitches in the sides, pain in the

back between the shoulder blades, hoarseness, loss of voice, sore throat, and bronchitis, with rattling in the windpipe and soreness of the chest, whereas the article would not be efficacious for such purposes; and, Section 502 (e) (1), the label failed to bear the common or usual name of the article, sodium bicarbonate.

DISPOSITION: On October 24, 1944, the defendant having entered a plea of not guilty, the case came on for trial before a jury. At the conclusion of the trial, the jury rendered a verdict of guilty, and on October 25, 1944, the court imposed a sentence of 6 months in jail, which was suspended, and placed the defendant on probation for 5 years.

1560. Misbranding of Thymus Arthritis Treatment, Liniodol, and Breasts of Youth Capsules. U. S. v. Dr. Jean Paul Fernel. Plea of not guilty. Tried to the court; verdict of guilty. Sentence of 1 year in jail, plus fine of \$500. Conviction affirmed on appeal. (F. D. C. No. 8819. Sample Nos. 14001-E, 61980-E, 80691-E, 82103-E.)

INFORMATION FILED: April 20, 1943, Northern District of Illinois, against Dr. Jean Paul Fernel, Chicago, Ill.; amended information filed October 25, 1943.

ALLEGED SHIPMENT: Between March 23 and July 4, 1942, from the State of Illinois into the States of California, Oregon, Ohio, and Florida.

PRODUCT: Analyses disclosed that the *Thymus Arthritis Treatment* was in the form of capsules containing salt and a mixture of glandular and plant materials; that the *Liniodol* consisted essentially of linseed oil, and that the *Breasts of Youth Capsules* contained glandular material and mineral matter including compound of aluminum and silicon.

NATURE OF CHARGE: *Thymus Arthritis Treatment*, misbranding, Section 502 (a), the name of the article was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of arthritis, whereas it would not be efficacious for those purposes; and certain statements on the label of the article and in accompanying circulars entitled "Arthritis Diet" and "Arthritis and Its Modern Treatment" were false and misleading since they represented and suggested that the article, when used in conjunction with the diet recommended in the circular entitled "Arthritis Diet" and in accordance with the treatments recommended in the circular entitled "Arthritis and Its Modern Treatment," would be efficacious in the cure, mitigation, treatment, or prevention of arthritis, whereas the article, either alone or in conjunction with the diet, and when used as directed or otherwise, would not be efficacious for those purposes; and, Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient and the quantity or proportion of thyroid in the article.

Liniodol, misbranding, Section 502 (e) (1), the label did not bear the common or usual name of the article, linseed oil; and, Section 502 (f) (1), the label failed to bear adequate directions for use since the directions, "15 drops during the meal in one teaspoonful of lemon juice, taken three times daily," did not inform the reader of the use or uses for which the article was intended, and were therefore inadequate.

Breasts of Youth Capsules, misbranding, Section 502 (a), the name of the article and certain label statements were false and misleading since they represented and created the impression that the article would be efficacious to correct underdeveloped, atrophied, flabby, and pendulous breasts; that it would be efficacious to develop in the consumer the firm, well-developed breasts of youth; and that it would be efficacious to develop and nourish the bust or breasts, whereas the article would not be efficacious for those purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient.

The *Breasts of Youth Capsules* and certain other articles known as *Essence No. 7*, *Fernel Nerve & Brain Food*, and *Endocrin Rejuvenation Food* were alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On November 10, 1943, the defendant having entered a plea of not guilty, the case came on for trial before the court. On November 16, 1943, the defendant was found guilty by the court and was sentenced to serve 1 year in jail and to pay a fine of \$500. Notice of appeal to the United States Circuit Court of Appeals for the Seventh Circuit was filed by the defendant on November 19, 1943, and on October 3, 1944, a decision was handed down by that court, affirming the decision of the district court.

1561. Misbranding of Nembutal Capsules and sodium phenobarbital capsules. U. S. v. H. Otis Fadal. Plea of guilty. Fine, \$600; sentence of 6 months in jail. Jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 14237. Sample Nos. 60900-F, 61558-F, 61561-F.)

INFORMATION FILED: February 27, 1945, Western District of Texas, against H. Otis Fadal, a member of the partnership trading as Fadal's Square Drug Store, at Waco, Tex.

INTERSTATE SHIPMENT: Between the approximate dates of December 11, 1943, and April 12, 1944, from Chicago, Ill., and Kansas City, Mo., of quantities of *Nembutal Capsules* and *sodium phenobarbital capsules*.

LABEL, WHEN SHIPPED: "Capsules Nembutal * * * (Pentobarbital Sodium, Abbott) Warning: May be habit forming 1½ grs. * * * Caution: To be used only by or on the prescription of a physician or dentist * * * Abbott Laboratories," or "Filled Capsules Phenobarbital Sodium 1½ Grs. (Barbituric Acid Derivative) Yellow Warning May Be Habit Forming Caution: To be used only by or on the prescription of a physician SE M CO The S. E. Massengill Co. * * * Bristol, Tenn.-Va."

NATURE OF CHARGE: That, between the dates of April 10 and May 8, 1944, the defendant removed a number of capsules from one of the bottles labeled "Capsules Phenobarbital" and repacked the capsules into an unlabeled bottle; that, on or about May 8, 1944, the defendant removed from the unlabeled bottle a number of capsules, repacked them in an unlabeled envelope, and sold them without a prescription; and that, on May 9, 1944, the defendant removed a number of capsules from the unlabeled bottle, repacked them in an envelope labeled "Nembutal 1½ gr." and sold them without a prescription. The information also charged that, on or about May 9, 1944, the defendant removed from the bottle labeled "Capsules Nembutal" a quantity of capsules and repacked them in an envelope bearing the label "Nembutal 1½ gr."

The information charged further that the acts of the defendant resulted in the drugs being misbranded in the following respects: Section 502 (d), the drugs contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming, and the envelopes bore no labels containing the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502 (f) (1), the envelopes bore no labeling containing directions for use; Section 502 (f) (2), they bore no labeling containing warnings against use in those pathological conditions where the use of the drugs might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users; Section 502 (e), the envelopes containing the *phenobarbital capsules* failed to bear a label containing the common or usual name of the drug, "Sodium Phenobarbital"; and, Section 502 (a), the label statement "Nembutal," borne on one of the envelopes containing the *phenobarbital capsules*, was false and misleading.

DISPOSITION: March 1, 1945. A plea of guilty having been entered by the defendant, the court imposed a fine of \$600 and sentenced the defendant to serve 6 months in jail. The jail sentence was suspended, and the defendant was placed on probation for 2 years.

1562. Misbranding of Col-Chex, Diarrhea and Flux Remedy, and Coldex. U. S. v. C. B. Drug Sales Co., Inc. Plea of guilty. Fine, \$100. (F. D. C. No. 11332. Sample Nos. 35395-F to 35397-F, incl.)

INFORMATION FILED: February 14, 1944, Western District of North Carolina, against the C. B. Drug Sales Co., Inc., Charlotte, N. C.

ALLEGED SHIPMENT: Between the approximate dates of December 31, 1942, and March 11, 1943, from the State of North Carolina into the State of South Carolina.

PRODUCT: Analyses disclosed that the *Col-Chex* was composed of a mineral oil base containing camphor, menthol, oil of Eucalyptus, and ephedrine; that the *Diarrhea and Flux Remedy* was a mixture containing salol, chalk, sodium phenolsulfonate, bismuth salicylate, and plant material; and that the *Coldex* was a mixture containing 20.4 grains of sodium salicylate per fluid ounce and also containing menthol and camphor, emodin-bearing drugs, and other plant material.

NATURE OF CHARGE: *Col-Chex*, misbranding, Section 502 (a), the label statements, "Col-Chex for Nose & Throat * * * Col-Chex is recommended as an aid in preventing colds and to check acute symptoms of trouble in nasal

passages. Repeat dosage every two hours until relieved," were false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of colds nor in the treatment of all acute symptoms of trouble in the nasal and throat passages; and certain statements in an accompanying leaflet regarding another drug, *Coldex*, were false and misleading, since they represented and suggested that the other drug would be efficacious in the cure, mitigation, treatment, or prevention of colds, coughs, and flu, and that the use of the other drug would often save the whole family from a period of sickness, whereas the other drug would not be efficacious for those purposes.

Diarrhea and Flux Remedy, misbranding, Section 502 (a), the label statements, "Diarrhea and Flux Remedy An efficient Antiferment and intestinal antiseptic and astringent for the treatment of Diarrhea, Dysentery, Colitis and Flux," were false and misleading since the article would not be an efficacious remedy in the cure, mitigation, treatment, or prevention of diarrhea or flux and would not be an efficient antiferment or intestinal antiseptic or astringent for the treatment of diarrhea, dysentery, colitis, or flux.

Coldex, misbranding, Section 502 (a), the name "Coldex" was misleading in that it represented and implied that the article would be a competent treatment for colds, whereas it would not be a competent treatment for colds; and the label statement "For Relief of Colds" was false and misleading since the article would not be an effective treatment for the relief of colds. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that the directions, "Two Teaspoonfuls in Water Then one teaspoonful every three or four hours until bowels move freely. Thereafter three times a day until desired results are obtained," suggested continuous use of the article, whereas the article was a laxative, and frequent or continued use might result in dependence upon laxatives to move the bowels; and, Section 502 (f) (2), the labeling of the article failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives to move the bowels.

DISPOSITION: April 9, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$100.

1563. Alleged misbranding of Heron's Constipation Remedy and Liver Regulator and Heron's Pure Eucalyptus Oil. U. S. v. Norman C. Heron (N. C. Heron Co.). Motion to strike granted and demurrer sustained. Case appealed and subsequently dismissed upon the death of the defendant. (F. D. C. No. 11399. Sample Nos. 14862-F to 14864-F, incl., 36429-F, 36430-F, 39904-F.)

INDICTMENT RETURNED: June 14, 1944, Southern District of California, against Norman C. Heron, trading as the N. C. Heron Co., Los Angeles, Calif.

ALLEGED SHIPMENT: Between the approximate dates of July 23 and August 26, 1943, from the State of California into the States of Oklahoma and Colorado.

PRODUCT: Analyses of samples disclosed that the *Constipation Remedy and Liver Regulator* consisted essentially of extracts of plant drugs including a laxative drug such as *cascara sagrada*; and that the *Heron's Pure Eucalyptus Oil* consisted of an oil of *Eucalyptus*.

NATURE OF CHARGE: *Constipation Remedy and Liver Regulator*, misbranding, Section 502 (a), the name of the article was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of all forms of constipation, and that it would be efficacious as a liver regulator, whereas the article would not be efficacious for the purposes claimed; and the label statements, "Harmless—Not Habit Forming," were false and misleading since the article might be harmful in the presence of appendicitis and might cause the formation of the laxative habit. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions on the label suggested frequent or continued use of the article, whereas it was a laxative and should not be used frequently or continuously; and, Section 502 (f) (2), the labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives to move the bowels.

Eucalyptus oil, misbranding, Section 502 (a), certain statements on the labels and in an accompanying circular were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of colds, coughs, whooping cough, croup, consumption,

diphtheria, catarrh, asthma, bronchitis, fever, headache, earache, toothache, neuralgia, sore throat, pleurisy, pneumonia, diabetes, stomach and kidney trouble, rheumatism, sprains, bruises, cuts, burns, insect bites, poison oak, and similar conditions indicated by the abbreviation "etc.," gravel, and wounds of all kinds; that the article was the most useful all around family remedy known for internal or external uses from the youngest to the oldest; that, when used in conjunction with *Heron's Liver Regulator*, it would be efficacious in the treatment of Bright's disease and diabetes; and that it would be efficacious in the treatment of colds or anything that originates from a cold, whereas the article would not be efficacious for the purposes claimed; and certain statements regarding another drug, *Heron's Constipation Remedy and Liver Regulator*, appearing in an accompanying circular, were false and misleading since they represented and suggested that the other drug was a wonderful relief for the liver, stomach, and bowels, diabetes, and the gall, whereas the other drug was not a wonderful relief for the liver, stomach, or bowels, diabetes, or the gall.

It was also alleged that the defendant had been previously convicted under the Federal Food, Drug, and Cosmetic Act.

DISPOSITION: The defendant subsequently filed a notice of motion to strike from the indictment the allegation of prior conviction and also filed a demurrer to the indictment as a whole for insufficiency and to the prior conviction pleaded therein. On July 10, 1944, the matter came on for hearing, at the conclusion of which the court granted the motion to strike and sustained the demurrer as to all counts of the indictment. On August 9, 1944, the Government filed a petition for an appeal from the district court to the Circuit Court of Appeals for the Ninth Circuit, setting forth that the action in granting the motion to strike the allegation of prior conviction in each count of the indictment and sustaining the demurrer to each count effected a final order setting aside the indictment. On the same date, an order was entered allowing the appeal. On February 20, 1945, following the death of the defendant, an order was entered by the appellate court, abating the action and dismissing the appeal.

1564. Adulteration and misbranding of balsam copaiba. U. S. v. 2 Cans of Balsam Copaiba. Default decree of forfeiture and destruction. (F. D. C. No. 12673. Sample No. 58676-F.)

LABEL FILED: On or about June 27, 1944, Western District of Virginia.

ALLEGED SHIPMENT: On or about March 13, 1944, by the McCormick Sales Co., from Baltimore, Md.

PRODUCT: 2 cans, each containing 29 pounds, of *balsam copaiba* at Apportion, Va. The product consisted essentially of a mixture of copaiba, cubeb, alum, and magnesium carbonate.

LABEL, IN PART: (Cans) "29 Lbs. Balsam Copaiba (Mixture) McCormick & Co. Manufacturing Chemists Baltimore, Md., U. S. A."

NATURE OF CHARGE: Adulteration, Section 501 (d), the substances cubeb, alum, and magnesium carbonate had been substituted in part for *balsam copaiba* (*mixture*).

Misbranding, Section 502 (a), the label statement, "Balsam Copaiba (Mixture)," was false and misleading as applied to the article, which consisted in part of cubeb, alum, and magnesium carbonate; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient in the article; and, Section 502 (f) (1), its label failed to bear adequate directions for use.

DISPOSITION: December 4, 1944. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1565. Misbranding of Pso-Ridisal. U. S. v. 180 Dozen Packages of Pso-Ridisal (and 6 other seizure actions against Pso-Ridisal). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 12916, 13398, 13399, 13401, 13595, 13596, 13611. Sample Nos. 59858-F, 63909-F, 66958-F, 66959-F, 68988-F, 86902-F, 87407-F.)

LABELS FILED: Between the approximate dates of July 27 and October 3, 1944, Northern District of Illinois, Southern District of Florida, Western District of Wisconsin, District of Kansas, and District of Colorado.

ALLEGED SHIPMENT: Between the approximate dates of May 11 and August 9, 1944, by the Sulfa Products Co., from Kansas City, Mo.

PRODUCT: *Pso-Ridisal*, 192 dozen packages at Chicago, Ill., 3 dozen packages at Miami, Fla., 5 dozen packages at LaCrosse, Wis., 21 dozen packages at Wichita, Kans., and 33 packages at Denver, Colo. Analyses of samples disclosed that

the article consisted essentially of sulfanilamide, carbolic acid, mineral oil, a trace of a saponifiable oil, and water.

NATURE OF CHARGE: Portion of article, misbranding, Section 502 (a). Certain statements on the labels of the article and in an accompanying booklet and leaflet entitled "Pso-Ridisal * * * A Sulfa Drug Compound" and "Miracles On the Home Front" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of acne, athlete's foot (ringworm), bed sores, burns, boils, dandruff, eczema, granulated wounds, infective ulcers of the skin, occupational dermatitis, psoriasis, barber's itch, and many other skin irritations, whereas the article would not be an effective medicament in the conditions mentioned. The following statements in the booklet and leaflet: "Is Pso-Ridisal Safe to use? Absolutely. In fact, Pso-Ridisal is so safe it can even be used on a baby's tender skin. In thousands of cases over a period of two and one-half years that Pso-Ridisal has been used, no harmful effects have been reported. * * * There is definite evidence that it is non-toxic as well as non-allergic. * * * Sulfanilamide * * * is absolutely harmless to normal skin tissue"; and "Latest medical reports confirm our findings that reaction from the use of Sulfanilamide are repeatedly negative, while the reaction from at least one of the more popular of the sulfa derivatives is persistently positive. We have found that Pso-Ridisal . . . the new physical form of Sulfanilamide can be used with every assurance of safety as an external treatment. Thousands of reports and many clinical tests give convincing confirmation of this fact" were false and misleading since the article was not safe, but was capable of producing untoward effects and of so sensitizing the user that subsequent administration of a sulfonamide might result in untoward reactions and, further, such sensitization might prevent the use of a sulfonamide in serious disease conditions. The legend "A Sulfa Drug Compound" and the statement "Pso-Ridisal, The New Physical Form of Sulfanilamide," appearing in the labeling of the article were false and misleading since they created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid, a saponifiable oil, and a mineral oil, which are pharmacologically active. The label statement, "Contains Phenol * * * and other inert ingredients," was false and misleading since phenol (carbolic acid) was not an inert ingredient.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual names of the active ingredients, carbolic acid, mineral oil, and a saponifiable oil; Section 502 (f) (1), the labeling of the article failed to bear adequate directions since the directions appearing in the labeling, "Impetigo: Wash affected area with warm water and mild soap. Dry skin thoroughly. Apply solution and massage gently. Open blebs and drain. Repeat application as often as necessary to lubricate skin [or "Keep skin lubricated"]," and "Washing and bathing should be restricted to normal requirements of cleanliness and comfort," did not constitute adequate directions for the use of the article in the treatment of impetigo; and, Section 502 (f) (2), the labeling failed to warn that the use of the article should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and it also failed to warn that the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

Remainder of article, misbranding, Section 502 (a). The legend "A Sulfa Drug Compound" and the designation "Pso-Ridisal," appearing in the labeling of the article, were false and misleading since they implied that the article would be effective for ridding the user of psoriasis, by reason of its content of sulfanilamide, whereas it would not be so effective. Certain statements appearing on the labels of the article and in accompanying booklets and leaflets entitled "Pso-Ridisal * * * A Sulfa Drug Compound," "A First in the Field of Proprietary Medicine," "Miracles On the Home Front," and "Good News for Skin Sufferers" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of acne, athlete's foot (ringworm), bed sores, cuts, burns, boils, dandruff, eczema, granulated wounds, infective ulcers of the skin, dermatitis, psoriasis, and many other skin irritations, whereas the article would not be efficacious for those purposes. The label statement on some packages, "Warning Initial application should be confined to a small area of body to permit comparison between treated and untreated parts. Should undesirable

reaction occur, discontinue use immediately and consult your physician. Use only as directed," created the misleading impression that the only potentially harmful effect the article might have was the causing of a visible or otherwise recognizable reaction on the small area of the body treated, and the statement was also misleading because it failed to reveal the fact, material in the light of the representation, that use of the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions, and that such sensitization might not be recognized by the user. The legend "A Sulfa Drug Compound," appearing in the labeling of the article, was misleading since it created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid and mineral oil, which are pharmacologically active.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, carbolic acid; Section 502 (f) (1), the following label statements on some packages did not constitute adequate directions for the use of the article in the treatment of impetigo: "Directions This preparation is intended * * * to soothe * * * irritation and discomfort resulting from such skin diseases as * * * Impetigo * * * Shake well before using and then apply locally by a gentle finger massaging of affected parts," and "Impetigo: Wash affected area with warm water and mild soap. Dry skin thoroughly. Apply solution and massage gently. Open blebs and drain. Repeat application as often as necessary to keep the skin lubricated"; and, Section 502 (f) (2), the labeling of the article failed to warn that its use should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and it also failed to warn that the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

DISPOSITION: May 28, 1945. The Nu-Basic Product Co., Royal Oak, Mich., claimant, having admitted the facts of the libels, and the cases having been consolidated for trial in the Northern District of Illinois, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1566. Misbranding of Pso-Ridisal. U. S. v. 1,233 Dozen Bottles of Pso-Ridisal (and 2 other seizure actions against Pso-Ridisal). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 13314, 13415, 13627. Sample Nos. 81350-F, 81385-F, 81399-F.)

LIBELS FILED: Between the approximate dates of August 11 and September 11, 1944, Western District of Missouri; amended libels filed on or about September 12, 1944.

ALLEGED SHIPMENT: Between the approximate dates of April 19 and August 29, 1944, by the Nu-Basic Product Co., from Royal Oak, Mich.

PRODUCT: 1,302½ dozen bottles of *Pso-Ridisal* at Kansas City, Mo. Analyses of samples disclosed that the product consisted essentially of sulfanilamide, carbolic acid, mineral oil, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a). The legend "A Sulfa Drug Compound" and the designation "Pso-Ridisal," appearing on the label of the article, were false and misleading since they implied that the article would be effective for ridding the user of psoriasis, by reason of its content of sulfanilamide, whereas it would not be so effective. The label statement, "This preparation is intended * * * to soothe the * * * irritation and discomfort resulting from such skin diseases as Psoriasis, Dermatitis, Eczema, * * * Athlete's Foot and Dandruff, and to assist in removing * * * unsightly lesions, was false and misleading because the article would not be effective to soothe the irritation and discomfort resulting from psoriasis, dermatitis, eczema, athlete's foot, and dandruff, or to assist in removing unsightly lesions. The label statement, "Warning Initial application should be confined to a small area of the body to permit comparison between treated and untreated parts. Should undesirable reaction occur, discontinue use immediately and consult your physician. Use only as directed," created the misleading impression that the only potentially harmful effect the article might have was the causing of a visible or otherwise recognizable reaction on the small area of the body treated, and it failed to reveal the fact, material in the light of such representation, that use of the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease

conditions, and that such sensitization might not be recognized by the user. The legend appearing on the label, "A Sulfa Drug Compound," was misleading since it created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid and mineral oil, which are pharmacologically active.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, carbolic acid; Section 502 (f) (1), its labeling failed to bear adequate directions for use in the treatment of impetigo, for which purpose the article was offered, since the label statement, "Directions This preparation is intended * * * to soothe * * * irritation and discomfort resulting from such skin diseases as * * * Impetigo * * * Shake well before using and then apply locally by a gentle finger massaging of affected parts," did not constitute adequate directions for use of the article in the treatment of impetigo; and, Section 502 (f) (2), the article contained sulfanilamide and its labeling failed to bear a warning that its use should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and that the article might sensitize the user of sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

DISPOSITION: The Nu-Basic Product Co. appeared as claimant and filed a motion to dismiss on the ground that a libel proceeding was pending in another district based upon the same misbranding as alleged in the instant actions, and that there had been no prior judgment in favor of the Government which would authorize multiple seizures of the product. The motion was subsequently overruled with the filing of amended libels which incorporated the allegations that the labeling had been found by the Commissioner of the Food and Drug Administration to be in a material respect misleading to the injury or damage of the purchaser or consumer of the product, and that an article of like composition and substance to the product, and labeled and branded almost exactly, had been previously the subject of a libel action which resulted in the condemnation of the article for having been misbranded. Thereafter, the cases were consolidated and removed for trial to the Northern District of Illinois, and on May 28, 1945, the claimant having admitted the facts in the libels, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1567. Adulteration of wild cherry bark. U. S. v. 1 Drum of Wild Cherry Bark. Default decree of condemnation and destruction. (F. D. C. No. 13091. Sample No. 77432-F.)

LIBEL FILED: July 28, 1944, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 4, 1943, by S. B. Penick and Co., from Jersey City, N. J.

PRODUCT: 1 100-pound drum of *wild cherry bark* at Long Island City, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects, insect parts, insect larva capsules, mites, rodent hair fragments, cat hair fragments, human hair fragments, and feather fragments; Section 501 (a) (2), it had been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth; and, Section 501 (b), it purported to be and was represented as *wild cherry bark*, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not substantially free from extraneous animal material and animal excreta, as required by the standard.

DISPOSITION: July 25, 1945. The sole intervener having withdrawn his claim, judgment of condemnation was entered and the product was ordered destroyed.

1568. Adulteration of Lobelia herb. U. S. v. 4 Bales of Lobelia Herb. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 12977. Sample No. 68461-F.)

LIBEL FILED: July 17, 1944, Southern District of Ohio.

ALLEGED SHIPMENT: On or about August 5, 1943, from Asheville, N. C.

PRODUCT: 4 bales of *Lobelia herb* at Cincinnati, Ohio, in the possession of Lloyd Brothers Pharmacists, Inc. The product was stored under insanitary conditions after shipment. The bales were torn, and they contained numerous rodent pellets. Examination showed that the product had become contaminated with rodent excreta.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance; and, Section 501 (a) (2), it had been held under insanitary conditions whereby it might have become contaminated with filth.

DISPOSITION: May 10, 1945. S. B. Penick & Co., Asheville, N. C., having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond, conditioned that the unfit portion be segregated and destroyed under the supervision of the Food and Drug Administration.

1569. Adulteration of crude drugs. U. S. v. 25 Bags of Jamaica Ginger (and 19 other seizure actions against crude drugs). Consent decrees of condemnation. Products ordered released under bond. (F. D. C. Nos. 13608, 13798. Sample Nos. 79066-F to 79075-F, incl., 79087-F to 79096-F, incl.)

LIBELS FILED: September 8 and 22, 1944, Eastern District of Michigan.

ALLEGED SHIPMENT: Between the approximate dates of September 11, 1939, and June 12, 1944, from Kingston, Jamaica, B. W. I., Artesia, Fla., West Jefferson, Lenoir, and Wilkesboro, N. C., Oakland, Calif., Jersey City, N. J., New York, N. Y., Cincinnati, Ohio, Big Timber, Mont., San Francisco, Calif., Louisville, Ky., and S. A. Bruxelles, Belgium.

PRODUCT: 25 bags of *Jamaica ginger*, 314 pounds of *chestnut leaves*, 20 bags and 28 drums of *saw palmetto berries*, 663 pounds of *red clover*, 2 bales of *red clover*, 3 sacks of *tonga vine*, 4 bales of *burdock root*, 45 bags of *burdock root*, 27 bags and 333 pounds of *goldenseal herb*, 7 bales and 1,062 pounds of *cotton root bark*, 14 sacks of *Arnica flowers*, 3,068 pounds of *poplar buds*, 339 pounds of *tonga bark*, 3,379 pounds of *white pine bark*, 308 pounds of *blue cohosh root*, 223 pounds of *squaw vine*, and 8 bags of *elder flowers*. The products were in the possession of Parke, Davis and Co., at Detroit, Mich.

An inspection of the building in which the products were stored after shipment revealed that the floors were broken in several places and that there were holes in the wall near the base boards, many of which showed evidence of rodent traffic. There were much dust and webbing about the premises. Some of the windows were broken, allowing ready access for rodents and insects. Numerous insects and rat excreta pellets were observed. Examination showed that the *Arnica flowers*, *saw palmetto berries*, *tonga bark and vine*, *squaw vine*, *elder flowers*, *Jamaica ginger*, *red clover*, *goldenseal herb*, and *burdock root*, and one lot of *cotton root bark*, were insect-infested, with some of them containing rodent hairs or rodent excreta.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the *Arnica flowers*, *saw palmetto berries*, *tonga bark and vine*, *squaw vine*, *elder flowers*, *Jamaica ginger*, *red clover*, *goldenseal herb*, *burdock root*, and one lot of the *cotton root bark*, consisted in whole or in part of filthy substances; and, Section 501 (a) (2), all products had been held under insanitary conditions whereby they might have become contaminated with filth.

DISPOSITION: December 26, 1944. Parke, Davis and Co., claimant, having admitted the allegations of the libels, judgments of condemnation were entered and the products were ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1570. Adulteration of Amylofene and Ephedrine Capsules. U. S. v. First Texas Chemical Manufacturing Co. Plea of not guilty. Tried to the court; verdict of guilty. Fine, \$50. (F. D. C. No. 14265. Sample Nos. 61004-F, 61139-F.)

INFORMATION FILED: March 7, 1945, Northern District of Texas, against the First Texas Chemical Manufacturing Co., a corporation, Dallas, Tex.

ALLEGED SHIPMENT: On or about July 17, 1942, and February 7, 1944, from the State of Texas into the State of Louisiana.

*See also Nos. 1552, 1564, 1567.

LABEL, IN PART: "Capsules Amylofene and Ephedrine Amylofene $\frac{3}{4}$ gr.
* * * Ephedrine Sulphate $\frac{3}{8}$ gr."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since it was represented to contain $\frac{3}{4}$ grain of *amylofene* and $\frac{3}{8}$ grain of *ephedrine sulfate* per capsule, whereas it contained, in one lot, not less than 0.856 grain ($\frac{6}{7}$ grain) of *amylofene* and not less than 0.432 grain ($\frac{3}{7}$ grain) of *ephedrine sulfate* per capsule; and it contained, in the remaining lot, not less than 0.876 grain ($\frac{6}{7}$ grain) of *amylofene* and not less 0.435 grain ($\frac{3}{7}$ grain) of *ephedrine sulfate* per capsule.

DISPOSITION: June 18, 1945. A plea of not guilty having been entered, the case came on for trial before the court. At the conclusion of the testimony and arguments of counsel, the defendant was found guilty and a fine of \$50 was imposed.

1571. Adulteration and misbranding of surgical pituitary. U. S. v. Bedwell Laboratories. Plea of not guilty. Tried to the court; verdict of guilty on count 1 and not guilty on count 2. Fine, \$750. (F. D. C. No. 12595. Sample No. 57660-F.)

INFORMATION FILED: November 1, 1944, Southern District of California, against Bedwell Laboratories, a corporation, Los Angeles, Calif.; charging the defendant with giving a false guaranty. The guaranty was given by the defendant to the Soltan Corporation, Los Angeles, Calif., on or about May 25, 1942. It provided that the article comprising each shipment or delivery made by the defendant to the latter firm would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On or about October 22, 1943, the defendant sold and delivered to the Soltan Corporation a quantity of the above-named product, and on or about October 23, 1943, the Soltan Corporation shipped from the State of California into the State of Texas a quantity of the product which had been delivered to it and guarantied by the defendant.

LABEL, IN PART: (Invoice) "Surgical Pituitary 20 Units."

NATURE OF CHARGE: Adulteration (count 1), Section 501 (d) (2), a pituitary preparation having a potency of 10 U. S. P. posterior pituitary units per cubic centimeter, commonly known as "obstetrical pituitary," had been substituted for *surgical pituitary* having a potency of 20 U. S. P. posterior pituitary units per cubic centimeter, which the article purported and was represented to be.

Misbranding (count 2), Section 502 (i) (3), the article consisted of obstetrical pituitary, and was offered for sale under the name of "Surgical Pituitary 20 Units."

DISPOSITION: April 3, 1945. A plea of not guilty having been entered on behalf of the defendant, the case came on for trial before the court. At the conclusion of the trial, the court returned a verdict of guilty on count 1 of the information and not guilty on count 2. On April 25, 1945, the defendant was fined \$750 on count 1.

1572. Adulteration and misbranding of pituitary extract, obstetrical. U. S. v. Chicago Pharmacal Co. Plea of guilty. Fine, \$200 and costs. (F. D. C. No. 10570. Sample No. 37767-F.)

INFORMATION FILED: May 4, 1945, Northern District of Illinois, against the Chicago Pharmacal Co., a corporation, Chicago, Ill.

ALLEGED SHIPMENT: On or about February 5, 1943, from the State of Illinois into the State of Indiana.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be posterior pituitary injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from and its quality fell below the official standard since it did not possess an activity equivalent to 1 U. S. P. posterior pituitary unit, as required by the Pharmacopoeia, but possessed an activity equivalent to not more than 0.67 U. S. P. posterior pituitary unit.

Misbranding, Section 502 (a), the label statement, "Each 1 cc. contains: Solution of Posterior Pituitary, U. S. P., 1 cc," was false and misleading.

DISPOSITION: June 12, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$100 on each of the 2 counts of the information, plus costs.

- 1573. Adulteration of thiamine hydrochloride. U. S. v. 807 Ampuls of Thiamine Hydrochloride. Default decree of condemnation and destruction.** (F. D. C. No. 13781. Sample No. 77567-F.)
- LABEL FILED:** September 16, 1944, Eastern District of New York.
- ALLEGED SHIPMENT:** On or about March 2, 1944, by John Wyeth & Brother, Inc., Philadelphia, Pa.
- PRODUCT:** 807 ampuls of thiamine hydrochloride at Long Island City, N. Y.
- LABEL, IN PART:** "Ampoule Solution Thiamine Hydrochloride * * * For Intravenous or Intramuscular Administration."
- NATURE OF CHARGE:** Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since an article intended for parenteral administration should be essentially free from undissolved material, whereas the article was contaminated with undissolved material.
- DISPOSITION:** November 15, 1944. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.
- 1574. Adulteration of spirits of camphor, isopropyl rubbing alcohol compound, and camphorated oil; and adulteration and misbranding of sweet oil and solution of boric acid. U. S. v. 62 Bottles of Spirits of Camphor, 106 Dozen Bottles of Isopropyl Rubbing Alcohol Compound, 25 Bottles of Solution of Boric Acid, 24 Bottles of Camphorated Oil, and 69 Bottles of Sweet Oil. Default decree of condemnation and destruction.** (F. D. C. No. 15125. Sample Nos. 3844-F, 3845-F, 3851-F, 3853-F, 3862-F.)
- LABEL FILED:** February 5, 1945, Western District of Oklahoma.
- ALLEGED SHIPMENT:** Between the approximate dates of July 18 and October 16, 1944, from Springfield, Mo., by T. Loveless, trading as the Loveless Pharmaceutical Co.
- PRODUCT:** 62 $\frac{1}{2}$ -ounce bottles of *spirits of camphor*, 106 dozen 16-ounce bottles of *isopropyl rubbing alcohol compound*, 25 4-ounce bottles of *solution of boric acid*, 24 2-ounce bottles of *camphorated oil*, and 69 1-ounce bottles of *sweet oil* at Enid, Okla.
- Analyses disclosed that the *spirits of camphor* contained not less than 11.78 grams of camphor in each 100 cc. and not more than 66.9 percent of alcohol, whereas the United States Pharmacopoeia provides that the product shall contain not more than 10.4 grams of camphor per 100 cc. and not less than 80 percent of alcohol; that the *isopropyl rubbing alcohol compound* contained not more than 49.96 percent by volume of isopropyl alcohol; that the *solution of boric acid* contained not more than 1.17 grams of boric acid per 100 cc., whereas the National Formulary provides that the product shall contain not less than 4.25 grams of boric acid per 100 cc.; that the *sweet oil*, which designation is recognized by the Pharmacopoeia as a synonym for olive oil, consisted essentially of cottonseed oil; and that the *camphorated oil* consisted of 11.26 percent of camphor dissolved in cottonseed oil, whereas the Pharmacopoeia provides that camphorated oil shall contain not less than 19 percent of camphor.
- NATURE OF CHARGE:** *Spirits of camphor and camphorated oil*, adulteration, Section 501 (b), the articles were represented as drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their strength differed from the standards set forth in the compendium.
- Isopropyl rubbing alcohol compound*, adulteration, Section 501 (c), its strength differed from that which it purported and was represented to possess, namely, "Isopropyl alcohol 70% by Volume."
- Solution of boric acid*, adulteration, Section 501 (b), it was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its strength differed from the standard set forth therein, and its difference in strength from the standard was not plainly stated on the label. Misbranding, Section 502 (a), the label statement, "Solution Boric Acid 4%," was false and misleading since the article did not contain 4 percent of boric acid.
- Sweet oil*, adulteration, Section 501 (d) (2), cottonseed oil had been substituted in whole or in part for olive oil. Misbranding, Section 502 (a), the statement "U. S. P. Sweet Oil" was false and misleading as applied to the article, which was not olive oil.
- DISPOSITION:** April 10, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1575. Adulteration of absorbent cotton. U. S. v. 11 Cartons of Absorbent Cotton. Default decree of condemnation. Product ordered delivered to the Food and Drug Administration. (F. D. C. No. 13889. Sample No. 61995-F.)

LABEL FILED: October 2, 1944, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about July 13, 1944, by New Aseptic Laboratories, Inc., from Columbia, S. C.

PRODUCT: 11 cartons, each containing 144 1-ounce packages, of *absorbent cotton* at New Orleans, La.

LABEL, IN PART: "Absorbent Cotton Sterilized After Packaging Distributed By Gotham Sales Co., Inc., New York."

NATURE OF CHARGE: Adulteration, Section 501 (b), the quality and purity of the article fell below the standard established by the United States Pharmacopoeia, which provides that absorbent cotton shall conform to the requirements of the official test for sterility of solids. The article was contaminated with living micro-organisms.

DISPOSITION: March 5, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed. On May 15, 1945, an amended decree was entered, providing for the delivery of the product for use in connection with the official laboratory work of the Food and Drug Administration.

1576. Adulteration and misbranding of prophylactics. U. S. v. Joseph Jacobs and Jack Katz. Pleas of guilty. Defendant Jacobs fined \$1,000; defendant Katz fined \$4,000 and placed on probation for 1 year. (F. D. C. No. 2107. Sample Nos. 10198-E, 10200-E.)

INFORMATION FILED: February 17, 1943, Southern District of New York, against Joseph Jacobs and Jack Katz, copartners trading under the name Joseph Jacobs, New York, N. Y.

ALLEGED SHIPMENT: On or about February 29 and March 6, 1940, from the State of New York into the State of New Jersey.

LABEL, IN PART: (Wrapper) "Excellent Quality"; (carton) "Pure Tex * * * Prophylactics"; (boxes) "Sold For Prevention of Disease Only."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the products fell below that which they purported or were represented to possess since they were represented to be excellent quality prophylactics, whereas they were defective because of the presence of holes.

Misbranding, Section 502 (a), the statements, "Excellent Quality," "Prophylactics," and "For Prevention of Diseases," were false and misleading since the products were not excellent quality prophylactics and would not be effective for the prevention of diseases since they were defective because of the presence of holes.

DISPOSITION: March 17, 1943. Pleas of guilty having been entered, the defendant Jacobs was fined \$1,000, and the defendant Katz was fined \$1,000 on each of the counts. The court placed the defendant Katz on probation for 1 year.

1577. Adulteration and misbranding of prophylactics. U. S. v. 8½ Gross of Prophylactics (and 7 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 15301, 15412, 15417, 15647, 15654, 15678. Sample Nos. 105-H, 809-H, 2589-H, 3609-H, 15357-H, 22909-H, 22910-H, 22913-H.)

LIBELS FILED: Between February 20 and March 31, 1945, Southern District of Florida, Western District of Virginia, Southern District of Indiana, Middle District of Georgia, Southern District of West Virginia, and Eastern District of Missouri.

ALLEGED SHIPMENT: Between the approximate dates of November 2, 1944, and February 28, 1945, by the Crown Rubber Sundries Co., from Akron, Ohio.

PRODUCT: *Prophylactics*, 8½ gross at Tampa, Fla., 7½ gross at Bedford, Va., 9¾ gross at Evansville, Ind., 8¼ gross at Sparks, Ga., 5 gross at Huntington, W. Va., and 3¼ gross at St. Louis, Mo. Examination of samples disclosed that the article was defective in that it contained holes.

LABEL, IN PART: "Red-Pak," or "Seal-Tex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements on the labels of portions of the article were false and misleading as applied to an article containing holes: (Red-Pak brand) "Prophylactics," "Guaranteed for five years," and

"For the prevention of disease"; (Seal-Tex brand) "Prophylactics," "The Pink of Perfection," "Made from the Highest Quality of Pure Milk of Rubber," "An Aid for the Prevention of Disease," and "For Prevention of Disease Only."

Further misbranding, Section 502 (b) (1) (2), a portion of the Red-Pak brand failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents.

DISPOSITION: Between March 28 and June 4, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1578. Misbranding of Kurex. U. S. v. Kurex Hillgrove Laboratories, Inc., Richard F. Hillgrove and Walter P. Weihe. Pleas of not guilty. Tried to the jury; verdict of guilty. Corporation given total fine of \$10,000, of which \$7,500 was suspended. Hillgrove sentenced to 2 years in jail and placed on probation for 3 years; Weihe sentenced to 30 days in jail and placed on probation for 1 year and 1 day. (F. D. C. No. 14312. Sample Nos. 904-H, 2535-H, 22014-H, 22016-H.)

INDICTMENT RETURNED: February 20, 1945, Southern District of Ohio, against the Kurex Hillgrove Laboratories, Inc., Cincinnati, Ohio, and Richard F. Hillgrove and Walter P. Weihe, officers of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of January 18 and February 5, 1945, from the State of Ohio into the States of Missouri, West Virginia, and Florida.

PRODUCT: Analyses of samples disclosed that the product was a dark brown liquid consisting chiefly of water, alcohol, and plant extractives, including an emodin-bearing drug.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying typewritten letter bearing the heading "Kurex" and an accompanying circular entitled "New Treatment For Diabetes" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of diabetes and such symptoms resulting from diabetes as a weakened, run-down condition, numb and cold legs and feet, and weak eyesight; and that the article would be effective to reduce excess blood sugar and to enable the diabetic to reduce the amount of insulin used and eventually eliminate the use of insulin. The article would not be efficacious for the purposes claimed.

It was also alleged that the defendants had been previously convicted under the Federal Food, Drug, and Cosmetic Act.

DISPOSITION: A motion to quash and a demurrer to the indictment were filed on behalf of the defendants, on the ground that the previous conviction of the defendants, to which reference was made in the indictment, was based upon a plea of nolo contendere. After a hearing in the matter, the court, on or about March 6, 1945, overruled the demurrer and denied the motion to quash. Thereafter, a plea of not guilty was entered for the defendants and the case came on for trial before a jury on March 14, 1945. At the conclusion of the trial on March 20, 1945, the jury returned a verdict of guilty, and on March 26, 1945, the following sentences were imposed: The corporation was fined \$2,500 on each of 4 counts of the indictment, with payment of the fine on all counts except count 1 being suspended; Richard F. Hillgrove was sentenced to serve 2 years in jail on count 1 and 15 months on count 2, the time to be served under those counts to run concurrently, and he also was given a suspended sentence of 3 years in jail on counts 3 and 4 and placed on probation for 3 years; Walter Weihe was sentenced to 30 days in jail on count 1, given a suspended sentence of 1 year and 1 day on each of the remaining 3 counts, and placed on probation for 1 year and 1 day.

1579. Misbranding of Prescription 1-VV-1 and Extract of Cod Liver. U. S. v. Sophia Strboya Sikoparija (Mrs. Stanley Sikoparija). Plea of not guilty. Tried to the jury; verdict of guilty. Fine, \$1,000. (F. D. C. No. 11380. Sample Nos. 29822-F, 33710-F.)

INFORMATION FILED: May 8, 1944, Eastern District of Texas, against Sophia Strboya Sikoparija, trading as Mrs. Stanley Sikoparija, Orange, Tex.

*See also Nos. 1551-1555, 1557, 1559-1566, 1572, 1574, 1576, 1577.

ALLEGED SHIPMENT: On or about January 20 and March 10, 1943, from the State of Texas into the States of California and Pennsylvania.

PRODUCT: Examination disclosed that the *Prescription 1-VV-1* contained sodium bicarbonate flavored with anise. The *Extract of Cod Liver* was a thick malt extract containing a small amount of fish oil or extractive and a small quantity of mineral matter including iron and phosphorus; it contained less than 1 U. S. P. unit of vitamin B₁ per gram and 4.6 micrograms of riboflavin (vitamin G) per milliliter.

NATURE OF CHARGE: *Prescription 1-VV-1*, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of chest colds, coughs, croup, influenza, grippe, flu, pain in the chest, difficult breathing, short, oppressed breathing, stitches in the side, pain in the back between the shoulder blades, hoarseness, loss of voice, sore throat, and bronchitis, with rattling in the windpipe and soreness of the chest, whereas the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article did not bear the common or usual name of the active ingredients.

Extract of Cod Liver, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article contained nux vomica; that it was rich in vitamins B and G; that it would be a beneficial tonic for normal growth in the young and normal health in all ages; that it would help to restore low vitality and build up the resistance in the body against infections and colds; that it would give the necessary elements to bone and body building; that it would be efficacious in the treatment of anemic conditions and in the treatment of people affected with lung ailments; and that it would improve the appetite and give strength and tone to the system. The article did not contain nux vomica; it was not rich in vitamins B and G, but contained inconsequential amounts of those vitamins; and it would not be efficacious for the purposes represented.

DISPOSITION: On October 24, 1944, the defendant having entered a plea of not guilty, the case came on for trial before a jury. At the conclusion of the trial, the jury returned a verdict of guilty, and on October 25, 1944, the court imposed a fine of \$1,000.

1580. Misbranding of Todd's Capsules. U. S. v. J. E. Todd, Inc. Plea of nolo contendere. Fine, \$250. (F. D. C. No. 12537. Sample Nos. 21830-F, 34113-F.)

INFORMATION FILED: August 21, 1944, Western District of New York, against J. E. Todd, Inc., Kenmore (Buffalo), N. Y.

ALLEGED SHIPMENT: On or about March 26 and June 11, 1943, from the State of New York into the State of Pennsylvania.

PRODUCT: Analyses of samples disclosed that the product consisted essentially of sand, carbonates or bicarbonates of calcium, magnesium and sodium, and an odorous resinous material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "This Folder May Prove a Message of Joy" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of rheumatism, arthritis, and neuritis, whereas the article would not be efficacious for those purposes.

DISPOSITION: June 11, 1945. A plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$125 on each of the two counts in the information.

1581. Misbranding of Munyon's Paw Paw Tonic. U. S. v. Phoenix Preparations and Clarence P. Wynne. Plea of guilty on behalf of the firm; plea of nolo contendere by the individual. Fine of \$250 against the firm; individual defendant given 6 months' suspended sentence and placed on probation for 1 year. (F. D. C. No. 14223. Sample No. 52843-F.)

INFORMATION FILED: April 11, 1945, Middle District of Pennsylvania, against Phoenix Preparations, a business association, Scranton, Pa., and Clarence P. Wynne, secretary-treasurer of the association.

ALLEGED SHIPMENT: On or about July 30, 1943, from the State of Pennsylvania into the State of Virginia.

PRODUCT: Analysis disclosed that the product consisted essentially of water, extracts of plant drugs including strychnine and an emodin-bearing drug together with a trace of an iron compound.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article and in an accompanying booklet entitled "Guide to Health" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of anemia, syphilis, dyspepsia, indigestion, dizziness, poor circulation, sleeplessness, nervousness, constipation, weakness, and general debility; that it would be efficacious as a digestant and a blood purifier; that it would be efficacious in toning the stomach, liver, and nerves; that it would be efficacious in the cure, mitigation, and treatment of persons who were overworked, weak, run-down, had no appetite, felt "old," whose blood was thin, whose heart was weak, who couldn't sleep, whose liver and stomach were out of order, and who were depressed and felt the need of new life; that the article would refresh and invigorate tired women; that it was a tonic for brain workers; that it would ironize the blood, increase body strength, aid the stomach, and increase mental force; that it possessed nerve and muscle building qualities; that it would be beneficial in building up the system when suffering from catarrh; that it would strengthen the stomach, aid digestion, and remove the cause of nervousness; that it would bring back strength and vitality; that it was an effective treatment for constipation, catarrh, and kidney and rheumatic complaints; that it would furnish rich blood to pale people, give life and snap to the overworked and run-down, and make the old folks feel strong; that it would drive out all poisons and impurities of the blood; that the juice of the papaw was more efficacious than pepsin in dissolving albumin and was an excellent vermifuge; and that the article was a great stomach, blood, heart, and nerve tonic. The article would not effect the results suggested or implied by the labeling.

Further misbranding, Section 502 (i) (1), the bottles containing the article were so made, formed, and filled as to be misleading, since they had long necks, were indented on sides, fronts, backs, and bottoms, and were closed with a long cork, by reason of which the bottles contained a smaller amount of the article than bottles of their size should contain.

DISPOSITION: May 22, 1945. Pleas of guilty and nolo contendere having been entered on behalf of the association and the individual defendant, respectively, the court imposed a fine of \$250 against the association and gave the individual defendant a 6 months' suspended sentence and placed him on probation for 1 year.

1582. Misbranding of Pancrezyme Tablets and Obeto Ampuls. U. S. v. Ziegler Pharmacal Co. Plea of guilty. Fine, \$400. (F. D. C. No. 14306. Sample Nos. 53727-F, 78209-F.)

INFORMATION FILED: April 17, 1945, Western District of New York, against the Ziegler Pharmacal Co., a partnership, Buffalo, N. Y.

ALLEGED SHIPMENT: On or about March 12 and 23, 1944, from the State of New York into the States of Pennsylvania and California.

PRODUCT: Analyses disclosed that the *Pancrezyme Tablets* contained enzymes such as pancreatin and an extract of bile; and that the *Obeto Ampuls* consisted of a water solution in ampuls, each 2 cubic centimeters of which contained an extract from 1 grain of thyroid.

NATURE OF CHARGE: *Pancrezyme Tablets*, misbranding, Section 502 (a), the label statement, "In mild cases of diabetes, Pancrezyme, combined with a restricted diet, has been found very efficient in reducing and controlling sugar," was false and misleading since the article would have no effect in reducing and controlling sugar in the treatment of diabetes.

Obeto Ampuls, misbranding, Section 502 (a), the label statement, "Active principles of adrenal cortex, anterior pituitary, * * * ovarian, lymphatic, pituitary posterior, thymus," created the false and misleading impression that the article contained the active principles of adrenal cortex, anterior pituitary, ovarian, and posterior pituitary in amounts sufficient to be of therapeutic importance, and that lymphatic and thymus tissues were active principles, whereas the article contained insignificant amounts of adrenal cortex, anterior pituitary, ovarian, and posterior pituitary, and lymphatic and thymus tissues contain no known active principles. Further misbranding, Section 501 (e) (2), the article was fabricated from two or more ingredients and contained a prepa-

ration of thyroid, but its label failed to bear a statement of the quantity or proportion of the preparation of thyroid.

DISPOSITION: May 10, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$200 on each count, a total fine of \$400.

1583. Misbranding of Contour-Molde "Face Lifting" Bandage. U. S. v. Eunice Skelly (Eunice Skelly House of Youth). Plea of guilty. Fine, \$300 and 6 months' suspended jail sentence. Defendant placed on probation for 6 months. (F. D. C. No. 11349. Sample No. 2273-F.)

INFORMATION FILED: August 4, 1944, Southern District of New York, against Eunice Skelly, trading as Eunice Skelly and the Eunice Skelly House of Youth, New York, N. Y.

ALLEGED SHIPMENT: On or about November 27, 1942, from the State of New York into the State of Illinois.

PRODUCT: A device known as the *Contour-Molde "Face Lifting" Bandage*, which was a part of a so-called "Deluxe Rejuvenating Kit" which contained various cosmetic preparations to be used in conjunction with the device.

The device was a strip of flesh-colored, elastic-weave cloth 17 inches long and 4 inches wide and stretching lengthwise only. Shipped with the device were certain circulars entitled "The Eunice Skelly Contour Molde," "Eunice Skelly presents her," and "Eunice Skelly's Brochure."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the device would be efficacious to lift the face, restore youthful contours to the face, and produce a passive massage action which would stimulate and support the muscles and thereby help prevent sagging of the muscles; that it would be efficacious to prevent and overcome sagging muscles, double chin, crepy throat and crepy neck; and that it would be efficacious to rejuvenate one physically and mentally. The article would not be efficacious for the purposes recommended and suggested.

The information also alleged that certain cosmetics which were to be used in conjunction with the device were misbranded under the provisions of the law relating to cosmetics, as reported in notices of judgment on cosmetics, No. 122.

DISPOSITION: August 10, 1944. A plea of guilty having been entered, the defendant was fined \$300 and sentenced to 6 months' imprisonment. The jail sentence was suspended and the defendant was placed on probation for 6 months.

1584. Misbranding of Bonquet Tablets. U. S. v. 1 Dozen Bottles and 9½ Dozen Bottles of Bonquet Tablets. Tried to the court. Case dismissed on motion. Appeal taken to United States Circuit Court of Appeals. Reversed and remanded. Consent decree of condemnation and destruction. (F. D. C. No. 8086. Sample Nos. 24605-F, 24606-F.)

LABEL FILED: August 10, 1942, District of Maryland; libel amended September 10, 1942, to cover seizure of additional lot of 2 ½ dozen bottles.

ALLEGED SHIPMENT: On or about April 1 and May 8, 1942, by the Bonquet Laboratories, from Glendale, Calif.

PRODUCT: 3¾ dozen 400-tablet bottles and 9½ dozen 150-tablet bottles of *Bonquet Tablets* at Baltimore, Md. Accompanying the product were a number of booklets entitled "Adds New Fighting Blood in 9 days." They had been shipped sometime prior to the shipment of the product.

Microscopic examination indicated that the product consisted essentially of dried brewer's yeast, milk sugar, dried leafy plant material, and approximately 1 grain of mineral matter per tablet.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements appearing in the labeling of the article were false and misleading in that they implied that the article, when taken as directed, would be a consequential supplement to the ordinary diet with respect to the minerals, fat, protein, carbohydrate, and caloric content, whereas it would not be a consequential adjunct to the diet with respect to those nutritional requirements: "Nutritional Data For Physicians And Dietitians Moisture . . . 10.11% Ash (Mineral Matter) . . . 10.81% Fat (Ether Extract) . . . 2.91% Protein (N x 6.25) . . . 33.25% Crude Fiber . . . 4.84% Carbohydrates other than crude fiber (by difference) . . . 38.08% Calories per pound . . . 1414 Total Alkalinity of Ash . . . 193 (No. of c.c. of 0.1 Normal acid required to neutralize the ash from

100 grams of Sample) * * * Mineral Analysis Calcium (Ca) 2.12% Magnesium (Mg) 0.18% Sodium (Na) 0.68% Phosphorous (P) 1.24% Manganese (Mn) 0.0035% Potassium (K) 4.08% Iron (Fe) 0.012% Copper (Cu) 0.0038% Chloride (Cl) 1.17% Iodine (I) Trace Sulfur (S) 0.40%."

Further misbranding, Section 502 (a), certain statements, designs, and devices appearing in the labeling were false and misleading since they suggested and engendered the idea in the mind of the reader that the article, when taken as directed, would prevent or correct abnormalities of the blood and thereby prevent or correct all disease conditions and specifically such conditions as rheumatic twinges, constipation, poor complexion, frequent headaches, numerous colds, dizziness, lack of appetite, tired feeling, loss of strength, pimples, boils, sallow complexion, poor skin, foul breath, heart palpitation, fatigue, despondency, listlessness, nervousness, anemia, pernicious anemia, and secondary anemia. The article would not prevent or correct abnormalities of the blood and thereby prevent or correct such disease conditions.

DISPOSITION: On October 14, 1942, J. Paul Elliott, receiver of Boncquet Laboratories, claimant, filed his claim and answer denying the allegations of misbranding. He also filed a motion to remove the case to the United States District Court for the Southern District of California. Thereafter, an answer to the claimant's motion was filed on behalf of the Government, alleging that there was no right of removal of the case to another district since a prior judgment in favor of the United States had been entered against Boncquet Tablets, based upon the same misbranding as that involved in the instant case. The claimant filed exceptions to the Government's answer and, after consideration of the evidence and arguments of counsel in the matter, the court, on January 22, 1943, entered an order denying the claimant's motion for removal.

On March 13, 1944, the district court ordered the libel dismissed with the following opinion:

COLEMAN, District Judge: "The Court having duly considered the motion of the claimant herein, J. Paul Elliott, Receiver of Boncquet Laboratories, to dismiss the amended libel against the articles, labels, circulars or pamphlets seized and described in the amended libel filed herein on the tenth day of September, 1942; and having also fully considered the answer of the Government to said motion of claimant, the Court is of the opinion that said motion should be granted for the following reasons: (1) The issues described in the amended libel forming the basis of this proceeding have, for all practical purposes, become moot in that the label appearing upon the bottles of the material seized, and also in that the accompanying circulars or pamphlets, have long ago been changed; and none of said material so labeled or said circulars or pamphlets have been distributed for more than two years, namely, since the twenty-eighth day of February, 1942; (2) the receiver of Boncquet Laboratories, claimant herein, has given assurances, under oath, to this Court, in his affidavit annexed to his motion to dismiss the amended libel herein, that hereafter no product of Boncquet Laboratories will be distributed under the former alleged objectionable label or formula and that no circulars or pamphlets will hereafter be issued of the alleged objectionable type; and (3) the receiver of Boncquet Laboratories, claimant in this proceeding, has received approval from the Superior Court for the State of California, in and for the County of Los Angeles, that being the Court wherein said receiver and claimant herein, received his appointment, for the use of a new label and future manufacture of the product of the Boncquet Laboratories under a changed formula and is under requirement of said Court to cease and desist from the use or distribution of the label, circulars or pamphlets or formula which are the subject matter of this present libel proceeding; and (4) prior to the hearing upon the merits conducted by the Court in this libel proceeding, all dealers in the alleged objectionable product of Boncquet Laboratories had been directed by said receiver of Boncquet Laboratories, to destroy any unused circulars or pamphlets of the alleged objectionable type described in the libel in this proceeding.

"In addition to the foregoing reasons for dismissing the amended libel, the Court is of the opinion that the long pending action by the Federal Trade Commission against Boncquet Laboratories, the institution of which action antedates the institution of the present proceeding, involves, for all practical purposes, the same issues that are involved in the present libel proceeding; that the representatives of the Government in the present libel proceeding have been unable to give to this Court any definite estimate as to when said action

by the Federal Trade Commission may be concluded; that presumably a decision in said action will ultimately be rendered and that to proceed with the present libel proceeding, under all of the circumstances, would thus appear to be duplicitous, costly and unnecessary.

"For the above reasons, an order will be signed herein granting the claimant's motion to dismiss the amended libel."

The Government perfected an appeal to the United States Circuit Court of Appeals for the Fourth Circuit, and the case was set for hearing and argued by counsel on November 13, 1944.

On December 13, 1944, the United States Circuit Court of Appeals handed down its decision reversing the judgment of the district court in dismissing the libel and remanding the case for further proceedings with the following opinion:

SOPEL, Circuit Judge: "The United States filed a libel for the seizure and condemnation of a quantity of drugs called Bonquet tablets, which had been shipped in interstate commerce from Glendale, California, to Baltimore, Maryland, on the ground that the goods were misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 21 U. S. C. A. § 301 et seq. The goods were attached and J. Paul Elliott, receiver of Bonquet Laboratories, by appointment of the Superior Court of Los Angeles County, California, filed an answer as claimant and prayed that the libel be dismissed.

"When the case came on for hearing, it was shown that the misbranding complained of appeared in certain descriptive circulars which were shipped separately from the goods and designed to be used by dealers in connection with the resale of the goods. In this instance the accused circulars had been shipped before the goods and the shipment of circulars of this kind had been discontinued before the shipment by the manufacturer of the attached goods; but the dealers, to whom the circulars and the goods had been sent, were not notified to withdraw the circulars until after the goods had been received and put on sale in Baltimore. Specifically the distribution of the circulars was discontinued on February 28, 1942. The goods were shipped in April and May, 1942, when the circulars were still in possession of the dealers, and the direction from the shipper to the dealers to destroy the circulars was not issued until August, 1942.

"Upon this set of facts the District Judge, before determining whether or not the circulars misdescribed the goods, ruled preliminarily that the circulars accompanied the goods within the meaning of § 321 (m) of the Act, so as to constitute a misbranding with the meaning of § 331 (b) of the Act, if in fact the circulars falsely described the goods. For decisions bearing on this subject see, *United States v. Research Laboratories*, 9 Cir., 126 F. 2d 42, 45; *certiorari denied* 317 U. S. 656, 63 S. Ct. 54, 87 L. Ed. 528; *United States v. Lee*, 7 Cir., 131 F. 2d 464, 466; *United States v. 7 Jugs, etc., Dr. Salsbury's Rakos*, D. C. Minn., 53 F. Supp. 746, 755.

"It was then brought to the attention of the court by attorneys for the claimant that a proceeding against the shipper of the goods, based upon similar misdescription of goods shipped in interstate commerce, had been instituted before the Federal Trade Commission prior to the filing of the libel in this case and was still pending. The court thereupon postponed the hearing of the libel so that it might be definitely ascertained whether the Federal Trade Commission intended to proceed with the case before it or to abandon it, with leave to the United States in the latter event or in the event that the same issues were not involved in the two proceedings, to move to put the libel case back on the trial docket of the District Court.

"Subsequently, the receiver and claimant of the goods filed a motion in the instant case supported by affidavit to dismiss the libel on the two grounds that the same issues were still pending before the Federal Trade Commission and that the instant case had become moot because after the libel was filed, the formula of the goods had been revised and the distribution of the circulars complained of had been discontinued. The court granted this motion and dismissed the case for the reasons and upon the findings of fact set out in an accompanying opinion. Therein the court held (1) that the issues in the libel case had become moot in that the label on the bottles and the accompanying circulars had been changed by the claimant and none of the drug so labelled or the accused circulars had been distributed for more than two years; (2) that the claimant had given assurances that there would be no further shipment of goods accompanied by the labels or circulars objected to; (3) that the claimant had obtained the approval of the California court for the use of a new label and the

manufacture of the goods under a changed formula, and had been ordered by that court to cease and desist from the distribution of the prior labels and circulars; (4) that all dealers had been directed to destroy the accused circulars and pamphlets, and (5) that for all practical purposes the same issues were involved in the pending action before the Federal Trade Commission so that to proceed with the libel case under the circumstances appeared to be duplicitous, costly and unnecessary.

"[1, 2] No copy of the complaint or of the answer or of the testimony taken in the proceeding before the Federal Trade Commission was introduced in evidence in the pending case, and the court's conclusion was based upon the general statement of counsel for the opposing parties that essentially the same issues were involved in both cases. In the absence of more definite proof, we shall assume that the jurisdiction of the Commission was invoked under the Federal Trade Commission statute, 15 U. S. C. A. §§ 45, 52, and 53, to enjoin the shipper of the drugs from using unfair or deceptive acts or practices and from disseminating false advertisements to induce the purchase of the drugs in interstate commerce. Obviously there is no necessary conflict between such a proceeding, which is designed to prevent the continuance in the future of unfair and deceptive trade practices, and a libel under the Federal Food, Drug, and Cosmetic Act which invokes the power of the court to seize and condemn falsely branded goods which have been unlawfully shipped in interstate commerce in the past. The relief sought in the libel suit, that is, the condemnation of the offending shipment could not have been granted by the Federal Trade Commission, and consequently it cannot be said that the court was clothed with that discretionary power to refuse to entertain jurisdiction which a court has when a prior action between the same parties involving the same issue has been filed in another court which has the power to adjudicate all the rights of the parties. There was no occasion for the application of the principle that the pendency of a prior action or suit, predicated on the same cause of action between the same parties, constitutes good ground for the abatement of a later action or suit. See *Maryland Casualty Co. v. Boyle Construction Co., Inc.*, 4 Cir., 123 F. 2d 558, 564. It has been correctly held that the power of the District Court to condemn misbranded articles is not impaired or affected by the power of the Federal Trade Commission to issue a cease and desist order against the shipper in a proceeding pending before it. *United States v. Research Laboratories, Inc.*, 9 Cir., 126 F. 2d 42, 45; *Sekov Corporation v. United States*, 5 Cir., 139 F. 2d 197.

"[3, 4] It is true that a decision of a court favorable to the manufacturer in a libel proceeding brought by the United States for the condemnation of goods alleged to have been misbranded is a bar to the promulgation of a cease and desist order by the Federal Trade Commission in a proceeding based on the same charge of misrepresentation of the character of goods shipped in interstate commerce; *George H. Lee Co. v. Federal Trade Commission*, 8 Cir., 113 F. 2d 583; and conversely it has been held that a libel to condemn goods alleged to have been misbranded under the Federal Food, Drug, and Cosmetic Act cannot be sustained if the Federal Trade Commission in a prior proceeding has found that the statements made by the shipper in respect to the goods were not false or misleading. *United States v. Willard Tablet Co.*, 7 Cir., 141 F. 2d 141. But there has been no determination by the Federal Trade Commission of the issues raised in the pending case. Indeed there is no definite showing of the precise status of the proceeding before the Commission. All we know is that a complaint was filed on December 8, 1938, some testimony was taken in California in September, 1942, and some effort has been subsequently made by the judge of the California court and by the claimant-receiver to induce the Federal Trade Commission not to issue a cease and desist order because the formula of the goods and the advertising matter relating thereto have been changed, and the shipper has directed the dealers to destroy all the old circulars on hand. What course the Federal Trade Commission will pursue in the future no one undertakes to say. For all that we know, the proceeding before that body may be abandoned or dismissed without further action. It seems clear that the claimant seeks the dismissal of the pending libel suit on the ground that the proceeding before the Federal Trade Commission involves the same issues and at the same time is seeking the dismissal of the latter proceeding on the ground that prior practices alleged to have been deceptive have been abandoned.

"[5] What has been said is a sufficient answer to the suggestion that the pending case is moot because the offending circulars have been withdrawn and

destroyed and the claimant has given the court assurance of good behavior in the future. Such a promise does not relieve the goods from liability for past actions and the case is not moot so long as the demand of the United States for condemnation of the goods remains unheard. Under the circumstances, we think that the trial court was not clothed with discretion or authority to decline jurisdiction. It should proceed to hear and determine the charges contained in the libel upon the merits since the right of a party litigant to the judgment of a court upon a matter properly before it is a fundamental aim of the law. *Cohen v. Virginia*, 6 Wheaton 264, 404, 5 L. Ed. 256, 257; *Willeox v. Consolidated Gas Co.*, 212 U. S. 19, 40, 29 S. Ct. 192, 53 L. Ed. 382, 48 L. R. A., N. S., 1134, 15 Ann. Cas. 1034; *McClellan v. Carland*, 217 U. S. 268, 282, 30 S. Ct. 501, 54 L. Ed. 762; 35 Am. Jur. (Mandamus) § 254, p. 25.

"The judgment of the District Court is reversed and the case remanded for further proceedings.

"Reversed."

Thereafter, on September 12, 1945, claimant having joined in requesting entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1585. Misbranding of Bonequet Tablets. U. S. v. 83 Bottles and 103 Bottles of Bonequet Tablets, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. No. 3677. Sample Nos. 26587-E, 26588-E.)

LIBEL FILED: January 21, 1941, Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of July 15 and November 6, 1940, by the Bonequet Laboratories, from Glendale, Calif.

PRODUCT: 83 400-tablet bottles and 103 150-tablet bottles of *Bonequet Tablets* at Seattle, Wash., together with a number of circulars entitled "Adds New Fighting Blood in 9 Days" and a number of placards and display cards.

Analysis showed that the product consisted essentially of yeast, milk sugar, salt, and desiccated green leaf and stem plant material, containing total iron 0.01 grain, total calcium calculated as calcium oxide 0.09 grain, total phosphorus calculated as phosphorus pentoxide 0.19 grain, and protein approximately 3 grains per tablet.

NATURE OF CHARGE: Misbranding, Section 502 (a), because of false and misleading curative and therapeutic claims in the labeling, substantially the same as those contained in the labeling of the same product reported in notices of judgment on drugs and devices, No. 1584.

Further misbranding, Section 502 (a), certain designs and statements in the labeling were false and misleading since they represented and suggested that the article contained the active principles of raw liver, vegetable iron, vitamin B complex, fortified with pure crystalline B and G, and assimilable calcium and phosphorus in therapeutically significant amounts. The article did not contain the ingredients mentioned in therapeutically significant amounts. Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: On March 27, 1941, Bonequet Laboratories having appeared as claimant, and stipulation having been entered between the United States attorney and the claimant for change of venue, the case was ordered transferred to the Northern District of California. On April 4, 1942, the case having been called and the claimant having failed to appear, judgment of condemnation was entered and the product was ordered destroyed.

1586. Misbranding of "666." U. S. v. 79 Dozen Bottles of "666" (and 10 other seizure actions against "666"). Decrees of condemnation and destruction. (F. D. C. Nos. 13086 to 13089, incl., 13801, 14650, 14664, 14665, 14849, 14862, 14863, 15280, 15724, 15804. Sample Nos. 72889-F to 72892-F, incl., 72896-F, 90145-F to 90148-F, incl., 90150-F, 90164-F to 90166-F, incl., 20312-H, 22320-H, 22321-H, 23814-H.)

LIBELS FILED: Between the approximate dates of July 31, 1944, and April 7, 1945, Northern Districts of Texas and California, Western District of Arkansas, Eastern District of Oklahoma, and District of Kansas.

ALLEGED SHIPMENT: Between the approximate dates of November 9, 1942, and May 29, 1944, by the Monticello Drug Co., from New Orleans, La.

PRODUCT: 324½ dozen bottles of "666," bottled in 3-ounce and 6-ounce containers and located at Dallas, Tex., San Francisco, Calif., Texarkana, Ark., Hot Springs, Ark., Nashville, Ark., Muskogee, Okla., Rogers, Ark., and Wichita, Kans.

Examination disclosed that the composition of the article, with the exception of the Muskogee lot, was essentially the same as that of the product which was the subject of seizure in the cases reported in notices of judgment on drugs and devices, No. 1231. The Muskogee lot contained epsom salt, citrated caffeine, iron chloride, and ammonium chloride dissolved in a mixture of water and glycerin, and it contained no quinine or other antimalarial. All lots of the article were similar in appearance and packaging to the drug which contained quinine sulfate and which was previously marketed by the Monticello Drug Co. for the treatment of malaria.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling on the bottles and carton was misleading in that the numerals "666," appearing on the labeling in red on a yellow background, and the yellow, red, and black color scheme of the other portions of the labeling, and the price of the article printed on the labeling, in combination constituted a statement and device which created the impression and belief that the article was the article of drug "666" which contained quinine sulfate and which was formerly for many years advertised, sold, and used as a treatment for malaria; Section 502 (i) (1), the container was so made, formed, and filled as to be misleading in that its shape, color, and appearance created the impression and belief that the article was the former product which contained quinine sulfate; Section 502 (i) (2), the product was an imitation of another drug in that its name, labeling, and color, and the color, shape, and appearance of the container, simulated the former product; and, Section 502 (i) (3), it was offered for sale under the name of another drug, the former product.

DISPOSITION: March 27, 1945. The Monticello Drug Co., claimant for the Wichita lot, filed an answer denying that the product in such lot was misbranded, to which the Government entered a plea of *res judicata*, alleging that the parties and the issues of the case of *The United States v. 70½ Dozen Bottles of "666,"* filed October 12, 1943, in the Middle District of Georgia, Valdosta Division, were identical with the present case, and that the court in that case had rendered a judgment in favor of the Government. The court, after hearing argument of counsel, sustained the Government's plea of *res judicata* and judgment was entered condemning the product and ordering its destruction. Between February 26 and June 6, 1945, the sole intervener in the action against the Dallas lot having consented to the entry of a decree, and no claimant having appeared for the remaining lots, judgments of condemnation were entered and the product was ordered destroyed.

1587. Misbranding of "666." U. S. v. 70 Bottles of "666." Decree of condemnation and destruction. (F. D. C. No. 15645. Sample No. 22319-H.)

LABEL FILED: On or about March 26, 1945, Western District of Missouri.

ALLEGED SHIPMENT: On or about November 3, 1944, by the Griffin Grocery Co., from Muskogee, Okla.

PRODUCT: 70 6-ounce bottles of "666" at Joplin, Mo. Analysis showed that the product contained epsom salt, citrated caffeine, iron chloride, and ammonium chloride, dissolved in a mixture of water and glycerin. It contained no quinine or other antimalarial. The article was similar in appearance and packaging to the drug which contained quinine sulfate and which was previously marketed by the Monticello Drug Co. for the treatment of malaria.

LABEL, IN PART: "666 Liquid * * * Monticello Drug Company, Jacksonville, Fla."

NATURE OF CHARGE: The article was alleged to be misbranded in the same manner as that of the product which was the subject of seizure in the cases reported in notices of judgment on drugs and devices, No. 1586.

DISPOSITION: April 23, 1945. The sole intervener having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1588. Misbranding of Monarch Vitamins. U. S. v. 3,453 Bottles of Monarch Vitamins. Default decree of condemnation and destruction. (F. D. C. No. 13413. Sample No. 54632-F.)

LABEL FILED: September 19, 1944, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 24, 1944, by the Cerophyl Laboratories, from Kansas City, Mo.

PRODUCT: 3,453 bottles, each containing 225 tablets, of Monarch Vitamins at Chicago, Ill.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular entitled "To Users of Monarch Vitamins," enclosed in the retail package containing the article, created the false and misleading impression that the article would be effective in the prevention or correction of poor appetite, nervousness, irritability, colds, and chronic constipation; that it would substitute for large quantities of fruits and vegetables as a source of vitamins and minerals; and that it was an ideal supplement, such as recommended by the Food and Nutrition Board of the National Research Council.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 8, 1944. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1589. Misbranding of vitamin C tablets. U. S. v. 137 Bottles, 260 Bottles, and 33 Bottles of Vitamin C Tablets. Default decree of destruction. (F. D. C. No. 14335. Sample Nos. 66983-F, 81093-F, 81094-F.)

LABEL FILED: On or about November 8, 1944, Western District of Missouri.

ALLEGED SHIPMENT: Between the approximate dates of July 3 and September 7, 1943, by Oxford Products, Inc., from Cleveland, Ohio.

PRODUCT: 137 bottles, each containing 40 25-milligram tablets, 260 bottles, each containing 40 50-milligram tablets, and 33 bottles, each containing 40 100-milligram tablets, of *vitamin C* at Kansas City, Mo.

The 50-milligram tablets were more than 50 percent deficient in vitamin C.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "Indicated as a vitamin supplement in dental caries, pyorrhea, certain gum infections, anorexia, anemia under nutrition and infections when these are consequences of a vitamin C deficiency," was false and misleading since it represented and suggested that the article would be efficacious in the treatment of the conditions stated, whereas the article would not be efficacious for such purposes.

Further misbranding, Section 502 (a), (50-milligram size tablets only) the label statement, "40 C. T. Tablets Vitamin C (Ascorbic Acid) 50 MG Each Tablet Contains 1000 U. S. P. Units of Vitamin C Which Is $1\frac{1}{2}$ Times Daily Requirements," was false and misleading.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 8297.

DISPOSITION: March 24, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1590. Misbranding of drug products. U. S. v. 994 Bottles of Rawleigh's Milk of Magnesia Tablets, 183 Bottles of Rawleigh's Castoria, 68 $\frac{1}{4}$ Dozen Bottles of Rawleigh's Ru-Mex-Ol Compound, 19 $\frac{1}{4}$ Dozen Bottles of Rawleigh's Milk of Magnesia, 109 Bottles of Rawleigh's Tonic Compound, 1,468 Packages of Rawleigh's Septo Powder for Poultry, 298 Packages of Rawleigh's Iodized Poultry Powder, and a number of catalogs. Decrees of condemnation. Ru-Mex-Ol Compound ordered destroyed; remaining products ordered released under bond. (F. D. C. No. 14633. Sample Nos. 8028-F, 8031-F to 8034-F, incl., 8037-F to 8039-F, incl.)

LABELS FILED: December 15, 1944, District of Minnesota.

ALLEGED SHIPMENT: By the W. T. Rawleigh Co., from Freeport, Ill. The various drugs were shipped between the approximate dates of April 4 and September 19, 1944. A number of the catalogs were enclosed in packages containing certain of the drugs. The remainder of the catalogs were shipped separately on or about June 28, 1944.

PRODUCT: The above-listed drugs, and accompanying catalogs entitled "Rawleigh's Good Health Products Consumers Catalog," at Minneapolis, Minn.

Analyses showed the following results: *Rawleigh's Milk of Magnesia Tablets* contained magnesium hydroxide flavored with peppermint; *Rawleigh's Castoria* consisted essentially of a laxative plant drug, Rochelle salt, sodium bicarbonate, sugar, water, and sodium benzoate, with a small proportion of wormseed; *Rawleigh's Ru-Mex-Ol Compound* consisted of extracts of plant drugs, including a laxative plant drug, potassium iodide, salicylic acid, sodium benzoate, alcohol, and water; *Rawleigh's Milk of Magnesia* consisted essentially of 8.43 percent of magnesium hydroxide and water; *Rawleigh's Tonic Compound* consisted essentially of water, sugar, phosphates, quinine, and alcohol, with small amounts of malt, and compounds of iron, manganese, and calcium; *Rawleigh's*

Septo Powder for Poultry consisted essentially of copper sulfate and potassium permanganate; and *Rawleigh's Iodized Poultry Powder* consisted essentially of phosphorus, calcium, iodine, sulfur, ferrous sulfate, ginger, and capsicum.

NATURE OF CHARGE: *Rawleigh's Milk of Magnesia Tablets*, misbranding, Section 502 (a), certain statements on the label and in the catalogs were false and misleading since they represented and suggested that the article would be effective in the treatment of indigestion, car sickness, severe burns and scalds, stomach discomfort, gas, nausea, vomiting, morning sickness of pregnancy, other stomach discomforts, seasickness, acid erosion of the teeth, and tooth sensitiveness and decay; and that as a mild laxative it had no habit forming properties. The article would not be effective in the treatment of the disease conditions mentioned and, when used as a laxative, would have the property of inducing the laxative habit.

Rawleigh's Castoria, misbranding, Section 502 (a), certain statements on the label and in the catalogs were false and misleading since they represented and suggested that the article would be effective in the treatment of simple diarrhea, wind colic, constipation, intestinal toxemia, bowel troubles and other disorders, sour eructations, belching, gas, nausea, acid dyspepsia, and worms. The article would not be effective in the treatment of the conditions stated.

Rawleigh's Ru-Mex-Ol, misbranding, Section 502 (a), certain statements on the label and in the catalogs were false and misleading since they represented and suggested that the article would be effective in the treatment of biliousness due to constipation, gas in the intestines, headache, rheumatism, impoverished blood, lack of appetite, slow digestion and elimination, and a run-down condition; and that it would be effective as a diuretic. The article would not be effective in the treatment of the conditions mentioned, including rheumatism, as was implied by the name *Ru-Mex-Ol*, and it would not be effective as a diuretic.

Rawleigh's Milk of Magnesia, misbranding, Section 502 (a), certain statements in the catalogs were false and misleading since they represented and suggested that the article would be effective in the treatment of simple diarrhea, sour stomach in infants, disorders due to teething, morning sickness of pregnancy, nausea, vomiting, seasickness, car sickness, acid disorders of the stomach, and severe burns and scalds. The article would not be effective in the treatment of the conditions stated.

Rawleigh's Tonic Compound, misbranding, Section 502 (a), certain statements in the catalogs were false and misleading since they represented and suggested that the article was a tonic and that it would be effective in the treatment of fatigue, restlessness, lack of appetite, slow digestion and elimination, impoverished blood, and a run-down system. The article was not a tonic and it would not be effective in the treatment of the conditions stated.

Rawleigh's Septo Powder for Poultry, misbranding, Section 502 (a), certain statements in the catalogs were false and misleading since they represented and suggested that the article would be effective in the control of chicken pox, croup, and contagious colds. The article would not be effective in the control of the conditions stated.

Rawleigh's Iodized Poultry Powder, misbranding, Section 502 (a), certain statements on the label and in the catalogs were false and misleading since they represented and suggested that the article would be useful to stimulate the appetite of poultry, early laying, and egg production; that it would increase the consumption of food and promote digestion and normal growth and production of poultry; and that it would keep fowls normally healthy and thrifty. The article would not be effective in producing the results stated and implied.

DISPOSITION: February 1 and 2, 1945. The W. T. Rawleigh Co., claimant for the *Milk of Magnesia*, *Milk of Magnesia Tablets*, *Tonic Compound*, *Septo Powder*, *Castoria*, and *Iodized Poultry Powder*, having admitted the material allegations of the libels, judgments of condemnation were entered and the products were ordered released under bond for relabeling under the supervision of the Food and Drug Administration. On November 4, 1945, no claimant having appeared for the *Ru-Mex-Ol Compound*, judgment of condemnation was entered and the product was ordered destroyed.

1591. Misbranding of Nokor. U. S. v. 57½ Dozen Packages of Nokor. Default decree of destruction. (F. D. C. No. 15097. Sample No. 97429-F.)

LIBEL FILED: On or about January 31, 1945, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 5, 1940, from Houston, Tex., by the Perl Products Co.

PRODUCT: $5\frac{1}{2}$ dozen packages of *Nokor* at Kansas City, Mo. Examination of a sample disclosed that the product consisted essentially of soap, calcium carbonate, lanolin, and small amounts of carbollic acid, castor oil, and camphor.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article and in an accompanying circular entitled "What it is and How to use Nokor" were false and misleading since they represented and suggested that the article would be efficacious in the treatment of boils, carbuncles, ingrown hairs, running sores, risings, blind boils, and other inflamed skin sores, whereas the article would not be efficacious for those purposes.

DISPOSITION: April 26, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1592. Misbranding of Miracle Aid for Wrinkles, Miracle Cream (Miracle Slenderizing Cream), and Miracle Bath. U. S. v. 27 Jars of Miracle Slenderizing Cream (and 12 other seizure actions against other lots of the same products and quantities of printed matter). Default decrees of condemnation and destruction. (F. D. C. Nos. 12507, 12775, 14189, 14372, 14374, 14436, 14718, 15772, 16070, 16123, 16149, 16630, 16664. Sample Nos. 41208-F, 68165-F, 68188-F, 68189-F, 68429-F, 68430-F, 68443-F to 68445-F, incl., 73305-F, 87484-F, 619-H, 620-H, 13057-H, 13058-H, 18246-H, 18247-H, 18584-H, 21829-H to 21831-H, incl., 29373-H, 29374-H.)

LABELS FILED: Between June 9, 1944, and June 29, 1945, Northern District of California, Northern and Southern Districts of Ohio, Northern District of Georgia, District of Minnesota, Western District of Tennessee, Northern District of Texas, and Southern District of Iowa.

ALLEGED SHIPMENT: Between the approximate dates of March 2, 1944, and May 24, 1945, by the Miracle Products Co., from Chicago, Ill., with the exception of certain printed matter at Toledo, Ohio, and San Francisco, Calif., which was shipped on or about October 28, 1944, and on other dates unknown, by the American Beauty Products Co., from Chicago, Ill.

PRODUCT: *Miracle Cream (Miracle Slenderizing Cream)*, 144 packages and 27 jars at San Francisco, Calif.; 12 jars and 28 packages at Cincinnati, Ohio; 29 jars at Dallas, Texas; 43 packages and 71 jars at Cleveland, Ohio; 68 jars at Toledo, Ohio; 15 jars at Atlanta, Ga.; 132 jars at Minneapolis, Minn.; 37 jars at Memphis, Tenn.; and 87 jars at Des Moines, Iowa. *Miracle Aid for Wrinkles*, 46 bottles and 15 packages at Cincinnati, Ohio; 77 packages at San Francisco, Calif.; 46 bottles at Cleveland, Ohio; 44 bottles at Atlanta, Ga.; and 16 bottles at Memphis, Tenn.; *Miracle Bath*, 4 packages at Toledo, Ohio; 13 sacks at Memphis, Tenn., and 32 packages at Des Moines, Iowa.

The printed matter accompanying the products consisted of leaflets entitled "The Miracle Plan," and "Wrinkles and Double Chin Vanish"; circulars entitled "For the Preservation and Enhancement of Beauty"; display cards entitled "Miracle Aid Lotion for Wrinkles and Double Chin," "Miracle Cream, A Simple and Safe Reducing Aid for Home Use," "Reduce Without Exertion in Your Own Bath Tub," and "Miracle Slenderizing Cream"; and a number of catalogs entitled "City Catalog No. 81."

Examination of the article known as *Miracle Slenderizing Cream* and *Miracle Cream* showed that it consisted essentially of epsom salts, water, stearate, and a small amount of methyl salicylate, with certain portions also containing sodium sulfate. Examination of the *Miracle Aid for Wrinkles* disclosed that it consisted essentially of water, small amounts of albumin, sodium sulfite, and perfume, with the exception of a portion which consisted essentially of water with small amounts of protein, sodium chloride, sodium benzoate, and perfume. Examination disclosed that the *Miracle Bath* consisted essentially of epsom salt, sulfur, and soap.

NATURE OF CHARGE: *Miracle Aid For Wrinkles*, misbranding, Section 502 (a), certain statements and designs on the label of the article and in accompanying labeling were false and misleading since they represented and suggested that the article would be efficacious to remove wrinkles and double chin, to feed skin tissues, pep up sluggish circulation, and activate important glands, whereas the article would not be efficacious for such purposes.

Miracle Cream (Miracle Slenderizing Cream), misbranding, Section 502 (a), certain statements on the label of the article and in certain of the accompanying printed matter were false and misleading since they represented and suggested that the article would be efficacious to bring about a reduction in weight, whereas the article would not be efficacious for that purpose.

Miracle Bath, misbranding, Section 502 (a), certain statements on its label and in certain of the display cards and leaflets were false and misleading since

they represented and suggested that the article would be efficacious in the reduction of weight and in the treatment of rheumatism and arthritis, whereas the article would not be efficacious for such purposes. Further misbranding, Section 502 (b), the label on a portion of the article failed to bear a statement of the quantity of the contents.

DISPOSITION: Between August 12, 1944, and September 26, 1945. No claimants having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1593. Misbranding of Presto for Blackheads. U. S. v. 108 Dozen Packages of Presto for Blackheads. Default decree of condemnation and destruction. (F. D. C. No. 9847. Sample No. 21698-F.)

LABEL FILED: April 22, 1943, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 25, 1943, by the McJohn Cosmetic Co., from Hollywood, Calif.

PRODUCT: 108 dozen packages of *Presto for Blackheads* at McKeesport, Pa. Examination showed that the product consisted of a stick composed essentially of a mixture of ground pumice and titanium dioxide, incorporated in a hydrated waxy base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements which appeared on the labeling were false and misleading as applied to the product, which was not effective in removing blackheads and in keeping the pores of the skin clean: "Presto for Blackheads Quick Aid for Blackheads * * * A clean skin is the foundation for a beautiful complexion; don't allow your complexion to be marred by unsightly Blackheads. Never squeeze or pinch Blackheads; Squeezing injures the skin and encourages large pores and Blackheads. Use Presto Stick and Eliminate Squeezing. * * * In cases of stubborn Blackheads use Presto Stick once daily for several days. Thereafter use from time to time, as required, to keep pores clean."

The article was also alleged to be misbranded as reported in notices of judgment on cosmetics, No. 124.

DISPOSITION: June 8, 1943. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1594. Misbranding of Astring-O-Sol. U. S. v. 90 Dozen Bottles and 114 Dozen Bottles of Astring-O-Sol. Default decree of destruction. (F. D. C. No. 6182. Sample No. 73243-E.)

LABEL FILED: On or about November 13, 1941; amended March 19, 1942, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 31, 1941, by the Nyal Co., from Detroit, Mich.

PRODUCT: Astring-O-Sol, 90 dozen 8-ounce bottles and 114 dozen 4-ounce bottles at Kansas City, Mo. Analysis showed that the product consisted essentially of 68 percent alcohol, 4.6 percent methyl salicylate, 0.38 percent zinc chloride, and water. Bacteriological examinations showed that in a concentration of 1 part of the product to 8 parts of water it was neither an antiseptic nor a germicide.

LABEL, IN PART: (Carton and bottle) "Astring-O-Sol * * * Concentrated Antiseptic Germicide An Astringent Mouth Wash Throat Gargle Economical To Use Refreshes Morning Mouth For Germicidal and Other Uses"; (carton) "a pleasant, refreshing Mouth Wash, Throat Gargle, Dentifrice, Gum Massage * * * This 4 oz. bottle makes 6 full pints of refreshing mouth wash and throat gargle"; (bottle) "Antiseptic Germicide Concentrated Directions As a Refreshing Mouth Wash, Gargle and for Offensive Breath Add Several Dashes of Ostring-O-Sol to One-Quarter Glass of water, but use enough to give a pleasant tingling sensation to the mouth."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading because it created the impression that the article, when used in the dilutions mentioned in the labeling as a mouth wash and throat gargle, would be antiseptic and germicidal, whereas in such dilutions and in dilutions of 1 part of the preparation to 8 parts water, a concentration greater than that recommended for mouth wash and throat gargle use, the article was neither antiseptic nor germicidal.

Further misbranding, Section 502 (i) (1), the container of the article was so made, formed, and filled as to be misleading since the bottle occupied less than 50 percent of the volume of the carton.

DISPOSITION: December 24, 1942. Frederick Stearns and Co., claimant, having withdrawn its answer to the libel with the permission of the court, judgment was entered ordering that the product be destroyed.

1595. Misbranding of Kaldak. U. S. v. 9 Cans and 12 Cans of Kaldak, and a number of circulars and leaflets (and 1 other seizure action against Kaldak and printed matter). Consent decree of condemnation. (F. D. C. No. 12487. Sample No. 77643-F, 77652-F.)

LIBELS FILED: May 31 and June 15, 1944, Eastern District of Pennsylvania; amended libel filed March 2, 1945, Western District of Michigan.

ALLEGED SHIPMENT: On or about May 1 and 27, 1944, by the Kaldak Co., from Lansing, Mich.

PRODUCT: 33 5-ounce cans and 24 12-ounce cans of *Kaldak* at Philadelphia, Pa.; also a number of accompanying circulars entitled "Faulty body chemistry may often contribute to symptoms of * * *" and leaflets entitled "Proof Aplenty about Kaldak."

Examination of a sample indicated that the product had essentially the composition stated on the label. Chemical analysis showed that the product contained, in each 10 grams, 0.52 gram of phosphorus, 0.45 gram of calcium, and 0.021 gram of iron.

LABEL, IN PART: "Kaldak A Dietary Food Supplement Providing Natural Vitamin B Complex, Vitamin D, Iron, Calcium and Phosphorus." The label also represented the product as containing dried brewer's yeast, reduced iron, dicalcium phosphate, and irradiated yeast.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets and circulars were false and misleading since they represented and suggested that the article would be effective in the treatment and prevention of a wide variety of diseases, conditions, and symptoms, including arthritis, neuritis, colitis, constipation, anemia, digestive disorders, chronic fatigue, high blood pressure, thyroid trouble, sinus trouble, low blood pressure, kidney, liver, and gall bladder trouble, nervousness, shortness of breath, heartburn, dizziness, nausea, poor appetite, gas on the stomach, indigestion, a run-down condition, general debility, stomach and intestinal irritation, sleeplessness, inability to concentrate, worry, fear, pains in arms, shoulders, legs, or thighs, soreness in joints or muscles, sciatica, headaches, chronic inflammation of the colon or lower bowel, diabetes, colds, rheumatic conditions, rheumatism, and rectal abscesses. The article would not be effective in the treatment and prevention of the diseases, conditions, and symptoms stated and implied.

DISPOSITION: On June 23, 1944, the libel proceedings were ordered consolidated, and on July 5, 1944, pursuant to motion of the Kaldak Company, the claimant, the case was ordered transferred to the district court for the Western District of Michigan.

Following the transfer of the case, and with the consent of the claimant, an amended libel was filed on March 2, 1945, to charge the misbranding of the product as a drug rather than as a food, as was set forth in the original libels. Thereafter, an answer was filed by the claimant, denying that the product was misbranded as charged in the amended libel.

On September 14, 1945, the claimant having withdrawn its answer and consented to the entry of a decree, judgment of condemnation was entered. A copy of the decree was subsequently transmitted to the United States attorney for the Eastern District of Pennsylvania, who thereupon issued instructions to the marshal for the destruction of the product.

DRUGS FOR VETERINARY USE*

1596. Misbranding of Russell's Korum and Russell's Spray Inhalant. U. S. v. I. D. Russell Co. Plea of nolo contendere. Fine, \$200 on count 1; sentence deferred on the remaining 3 counts. (F. D. C. No. 12553. Sample Nos. 6241-F to 6243-F, incl., 6955-F to 6957-F, incl., 28827-F, 28828-F.)

INFORMATION FILED: September 12, 1944, Western District of Missouri, against the I. D. Russell Co., a partnership, Kansas City, Mo.

ALLEGED SHIPMENT: Between the approximate dates of March 27 and May 29, 1943, from the State of Missouri into the States of Illinois and Georgia.

PRODUCT: Analyses of samples disclosed that the *Korum* consisted essentially of water containing small portions of sodium chlorate, potassium dichromate, potassium nitrate, sodium chloride, and epsom salt; and that the *Spray Inhal-*

*See also No. 1590.

ant consisted essentially of pine oil and oil of Eucalyptus, small proportions of menthol, camphor, and creosote, soap, and water.

NATURE OF CHARGE: *Korum*, misbranding, Section 403 (a), certain statements in the circulars entitled "Russell Poultry Medicines and Biologics," "Questions Often Asked by Poultry Raisers," "Turkey Pointers," "Chick Tips," and "Russell's Poultry Health and Disease Guide," which accompanied various shipments of the article, were false and misleading since they represented and suggested that the article would be efficacious in the prevention and treatment of worms which infest poultry, coccidiosis, mycosis, blackhead, trichomoniasis, colds, roup, bronchitis, tracheitis, and diarrhea; that it would maintain health of poultry; that it was a mild laxative; that it possessed astringent properties; that it would aid in dissolving and removing mucus and slime from the digestive and intestinal tract; and that it would stimulate the appetite, aid in the raising of stronger chicks and healthier, husky, pullets and broilers, and be effective in promoting growth, health, and production of poultry. The article was not a mild laxative, it did not possess astringent properties, and it would not be efficacious for the purposes claimed.

Spray Inhalant, misbranding, Section 502 (a), certain statements in the circulars entitled "Chick Tips," "Russell's Poultry Health and Disease Guide," "Questions Often Asked by Poultry Raisers," and "Turkey Pointers," which accompanied the article, were false and misleading since they represented and suggested that the article would be efficacious as an aid in the relief and control of respiratory diseases which affect poultry, such as colds, roup, bronchitis, and tracheitis; that, when used as directed, it would act as a cleansing medication for the nostrils, mouth, eyes, throat, and lungs; that it would act as a stimulant to the respiratory membranes; and that it would be efficacious in the maintenance of the health of poultry. The article would not be efficacious for the purposes claimed.

DISPOSITION: April 16, 1945. A plea of *nolo contendere* having been entered on behalf of the defendant, the court imposed a fine of \$200 on count 1 and deferred sentence for 1 year on the remaining 3 counts.

1597. Misbranding of Pratt's Poultry Regulator, Pratt's Animal Regulator, and Pratt's Poultry Inhalant. U. S. v. 40 Packages and 5 Drums of Pratt's Poultry Regulator, 6 Packages of Pratt's Animal Regulator, and 45 Bottles of Pratt's Poultry Inhalant. Default decree of condemnation and destruction. (F. D. C. No. 13820. Sample Nos. 78063-F to 78065-F, incl.)

LIBEL FILED: September 26, 1944, District of New Jersey.

ALLEGED SHIPMENT: On or about July 31, 1944, from Philadelphia, Pa., by the Pratt Food Co.

PRODUCT: 21 2¾-pound packages, 19 25-pound packages, and 5 100-pound drums of Pratt's Poultry Regulator; 6 2½-pound packages of Pratt's Animal Regulator; and 21 1-pint bottles and 24 1-quart bottles of Pratt's Poultry Inhalant at Brooklawn, N. J.

Analyses disclosed that the *Poultry Regulator* consisted essentially of calcium carbonate, with small proportions of iron oxide, copper sulfate, iodides, sulfur, and compounds of magnesium, manganese, nickel, and phosphorus, together with plant material including a strychnine-bearing drug; that the *Animal Regulator* consisted essentially of calcium carbonate, with small proportions of iron, copper, manganese, nickel, cobalt, and magnesium sulfates and carbonates, sulfur, and plant material, including a strychnine-bearing drug; and that the *Poultry Inhalant* consisted essentially of water, isopropyl alcohol, with small proportions of boric acid, formaldehyde, and eucalyptol.

NATURE OF CHARGE: *Poultry Regulator*, misbranding, Section 502 (a), certain label statements and certain statements on a poster entitled "More Eggs in 15 Days," in a booklet entitled "The Poultry Health Guide," and in a leaflet entitled "2¢ a Day Gets More Eggs from 100 Hens," which were shipped with the article, were false and misleading since they represented and suggested that the article would be effective to regulate the body functions of poultry; that it would be effective as a tonic and appetizer; that it would be effective to make ordinary feeding mash better and to increase egg production; and that it would be effective in the prevention or treatment of deficiency diseases, limber neck, canker, tuberculosis, pullet disease (blue comb), chicken pox, and diphtheria. The article would not be effective for such purposes.

Animal Regulator, misbranding, Section 502 (a), certain label statements and certain statements on a poster entitled "Keep Their Insides Earning" and in

a booklet entitled "The Poultry Health Guide," which were shipped with the article, were false and misleading since they represented and suggested that the article would be effective to regulate the body functions of animals and to increase the flow of digestive juices; that it would be effective as a tonic, when used as directed; that it would produce the benefits implied by the phrase "Where hastened benefits are desirable"; that it would guard the animals against deficiency diseases due to all causes; and that it would increase profits as implied by the statement "Keep Their Insides Earning." The article would not be effective for such purposes.

Poultry Inhalant, misbranding. Section 502 (a), certain statements on the label and in the booklet entitled "The Poultry Health Guide," which was shipped with the article, were false and misleading since they represented and suggested that the article, when used as a spray over poultry, as directed on the label, would be effective for the relief of coughs due to colds and for the relief of minor bronchial irritations; that it would be effective as a treatment for respiratory diseases of poultry; that it would cause poultry to cough and expel the exudate; and that it possessed inhibiting antiseptic properties within the respiratory tract. The article would not be effective for the purposes claimed and did not possess any inhibiting antiseptic properties within the respiratory tract.

DISPOSITION: March 2, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1598. Misbranding of Wonder Poultry Tonic and Morehog. U. S. v. 64 Bottles and 6 Jugs of Wonder Poultry Tonic and 21 Bottles of Morehog, together with accompanying labeling. Default decree of forfeiture and destruction. (F. D. C. No. 12624. Sample Nos. 40115-F, 40116-F.)

LABEL FILED: June 13, 1944, Western District of Wisconsin.

ALLEGED SHIPMENT: On or about April 10, 1944, by the Wonder Chemical Co., from Minneapolis, Minn.

PRODUCT: 42 1-quart bottles, 22 1-pint bottles, and 6 1-gallon jugs of *Wonder Poultry Tonic*, and 21 1-pint bottles of *Morehog*, together with accompanying labeling, at Ettrick, Wis. The labeling included a number of hand-out cards, placards, streamers, and posters.

Analyses of samples disclosed that the *Poultry Tonic* consisted essentially of water, with small proportions of epsom salt, sulfuric acid, iron sulfate, sodium phenolsulfonate, alum, and 0.1 percent of a volatile oil; and that the *Morehog* consisted essentially of water, with small proportions of iron sulfate, epsom salt, sulfuric acid, boric acid, iron oxide, and not more than 0.2 percent of volatile oils, including oil of wormseed.

NATURE OF CHARGE: *Poultry Tonic*, misbranding. Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article possessed significant therapeutic properties; that it was a tonic; that there was something wonderful about its composition; and that use of the article would prevent or cure disease conditions, thereby preventing losses in the raising of chicks. The article, when used as directed, had no value in the prevention and treatment of any disease condition affecting chicks and poultry.

Morehog, misbranding. Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article had medicinal value; that it would remove worms which infest hogs; that it was a tonic; that it was a conditioner; that it would cause hogs to gain more weight; that it was a stimulant to the appetite; and that it was beneficial to growing animals and those being fed for the market. The article had no medicinal value; it would not remove worms which infest hogs; it was not a tonic; it was not a conditioner, a term which implies that the article would improve the condition of hogs which were out of condition or off condition due to any number of causes, including disease; the article would not cause hogs to gain more weight, as the name "Morehog" and the statement in the labeling, "more hog gains," implied; it was not a stimulant to the appetite; and it consisted of nothing that was beneficial to growing animals and those being fed for the market.

DISPOSITION: September 21, 1944. No claimant having appeared, judgment of forfeiture was entered and the products, together with the accompanying labeling, were ordered destroyed.

1599. Misbranding of A. D. D.'s Save the Cow. U. S. v. 13 Bottles of A. D. D.'s Save the Cow. Default decree of condemnation and destruction. (F. D. C. No. 12239. Sample No. 65938-F.)

LABEL FILED: April 25, 1944, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 11, 1944, by A. D. Driscoll, from Whitney Point, N. Y.

PRODUCT: 13 bottles of *A. D. D.'s Save the Cow* at Honesdale, Pa. Analysis showed that the product consisted essentially of linseed oil, a lead compound, a sulfate, a nitrate, and volatile oils, including camphor.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling created the false and misleading impression that the article would be efficacious in the cure, mitigation, treatment, and prevention of garget and fowls, thrush, spider teat, swollen, caked udder, cuts, old sores, hoof rot, and lameness; that it would be effective as a penetrating, powerful healer; that it would cleanse the diseased parts, subdue inflammation, stimulate healthy granulation and absorb all inflammatory matter, and hasten the healing process; that it would allay inflammation, increase circulation, and give immediate relief in the most severe cases of caked bag, spider teat, garget, and all bunches in the teat, in two or three applications; and that it would give immediate relief in pricks, cracks, and corns in horses' feet, barbed wire fence cuts, fistula, poll evil, and old sores of any kind. The article would not be effective for the purposes suggested and implied in the labeling. Further misbranding, Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e), its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: September 6, 1944. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

HABIT-FORMING DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR WARNING STATEMENT*

1600. Misbranding of Novalene Tablets. U. S. v. 313,464 Packages of Novalene Tablets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 7805. Sample No. 89508-E.)

LABEL FILED: June 29, 1942, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of March 11 and June 10, 1942, by the Ivers-Lee Co., from Newark, N. J.

PRODUCT: 313,464 packages of *Novalene Tablets* at New York, N. Y. Examination of samples showed that each tablet contained 0.26 grain of phenobarbital, 0.40 grain of ephedrine sulfate, and 2.5 grains of potassium iodide, together with calcium lactate and starch.

LABEL, IN PART: "Novalene Tablets For Relief in Asthma and Hay Fever Professional Drugs, Inc., 80 Lafayette Street, New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the label of the article failed to reveal the fact that the name appearing on the label was the name of the distributor; Section 502 (b) (2), the label bore no statement of the quantity of the contents; Section 502 (d), the article was for use by man and it contained phenobarbital, a chemical derivative of barbituric acid, which derivative has by regulation been designated as habit forming, and its label failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: July 17, 1942. Professional Drugs, Inc., claimant, having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

*See also Nos. 1553, 1561.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 1551 TO 1600

PRODUCTS

	N. J. No.		N. J. No.
A. D. D.'s Save the Cow	1599	Miracle Aid for Wrinkles, Miracle Cream (Miracle Slen-	
Abortifacient	1552, ¹ 1558	derizing Cream), and Miracle Bath	1592
Aditis Capsules	¹ 1554	Monarch Vitamins	1588
Alcohol compound, isopropyl	1574	Morehog	1598
Amylofene and Ephedrine Capsules	¹ 1570	Munyon's Paw Paw Tonic	1581
Antiseptic	1594	N. K. Tablets	1556
Arnica flowers	1569	N. M. Tablets	1556
Astring-O-Sol	1594	Nembutal capsules	1561
Bonquet Tablets	² 1584, 1585	Nokor	1591
Boric acid, solution of	1574	Novalene Tablets	1600
Breasts of Youth Capsules	¹ 1560	Obeto Ampuls	1582
Bullock's System Self-Treatment for Sinus and Catarrhal Infection	³ 1551	Olive oil. <i>See</i> Sweet oil.	
Burdock root	1569	Palmetto berries. <i>See</i> Saw palmetto berries.	
C. C. Pills	1556	Pancreszyme Tablets	1582
Camphor, spirits of	1574	Parenteral drugs	⁴ 1571-1573
Camphorated oil	1574	Pine bark, white	1569
Cherry bark, wild	1567	Pituitary, obstetrical	1572
Chestnut leaves	1569	surgical	¹ 1571
Clover, red	1569	Poplar buds	1569
Cohosh root, blue	1569	Pratts Poultry Regulator, Animal Regulator, and Poultry Inhalant	1597
Col-Chex	1562	Prescription Medicine 1-B-7	¹ 1553
Coldex	1562	Prescription(s) 1-H-7	¹ 1553, ¹ 1559
Contour-Molde "Face Lifting" Bandage	1583	1-NN-1 Nerve Tablets, and 1-RR-7	¹ 1553
Copaiba, balsam of	1564	1-VV-1	¹ 1559, ¹ 1579
Cosmetics (subject to the drug provisions of the Act)	1592-1594	Presto for Blackheads	1593
Cotton, absorbent	1575	Prophylactics	1576, 1577
Cotton root bark	1569	Pso-Ridial	1565, 1566
Devices	1576, 1577, 1583	Rawleigh's Milk of Magnesia, Castoria, Ru-Mex-01 Compound, Tonic Compound, Septo for Poultry, and Iodized Poultry Powder	1590
Diarrhea and Flux Remedy	1562	Red Blood Purifier	¹ 1559
Dimels Capsules	¹ 1554	Reducing preparations	1555, 1592
Elder flowers	1569	Russell's Korum and Russell's Spray Inhalant	1596
External No. 1	¹ 1553	Saw palmetto berries	1569
Extract of Cod Liver	¹ 1579	"666"	1586, 1587
Face-lifting bandage	1583	Sodium phenobarbital capsules	1561
Ginger, Jamaica	1569	Squaw vine	1569
Goldenseal herb	1569	Stanley's Stomach Powder	¹ 1553
Heron's Constipation Remedy and Liver Regulator, and Heron's Pure Eucalyptus Oil	¹ 1563	Sweet oil	1574
Injection preparations. <i>See</i> Parenteral drugs.		Thiamine hydrochloride	1573
Interferin	1552, ¹ 1558	Thymus Arthritis Treatment	¹ 1560
Intrauterine paste	1552, ¹ 1558	Todd's Capsules	1580
Kaldak	1595	Tonga bark and tonga vine	1569
Kurex	¹ 1578	Tonic 1-X-1	¹ 1559
Lax Thyroid Tablets	1555	Veterinary preparations	1590, 1596-1599
Laxatives without required warning statements	¹ 1553, 1556, ¹ 1559, 1562, ¹ 1563	Vitamin B ₁ injection	1573
Liniodol	¹ 1560	C tablets	1589
Lobelia herb	1568	preparations	1573, ¹ 1579, 1585, 1588, 1589, 1595
Magnesia, milk of	1590	Wonder Poultry Tonic	1598
		Yuk-Air Compound	1557

¹ Prosecution contested.² Seizure contested. Contains opinions of the courts.³ Permanent injunction issued.⁴ (1571) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
American Beauty Products Co.:		Ivers-Lee Co.:	
printed matter-----	1592	Novalene Tablets-----	1600
Bedwell Laboratories:		Jacobs, Joseph:	
surgical pituitary-----	¹ 1571	nrophylactics-----	1576
Bonquet Laboratories:		Jones, C. W.:	
Bonquet Tablets-----	² 1584, 1585	Dimels Capsules and Aditis	
Bullock's Laboratories, Inc.:		Capsules-----	¹ 1554
Bullock's System Self-Treat-		Jones-Hague, Inc.:	
ment for Sinus and Cat-		Dimels Capsules and Aditis	
arrhal Infection-----	³ 1551	Capsules-----	¹ 1554
C. B. Drug Sales Co., Inc.:		Kaldak Co.:	
Col-Chex, Diarrhea and Flux		Kaldak-----	1595
Remedy, and Coldex-----	1562	Katz, Jack:	
Carolina Chemical Co. <i>See</i> Hid-		prophylactics-----	1576
den, E. S.		Keefer, D. C.:	
Cerophyl Laboratories:		Interferin-----	1552
Monarch Vitamins-----	1588	Keefer, Don:	
Chicago Pharmacal Co.:		Interferin-----	¹ 1558
pituitary extract, obstetrical--	1572	Keefer Laboratories. <i>See</i> Keefer,	
Crown Rubber Sundries Co.:		D. C.	
prophylactics-----	1577	Koutz, G. M.:	
Driscoll, A. D.:		Bullock's System Self-Treat-	
A. D. D.'s Save the Cow-----	1599	ment for Sinus and Catarrhal	
Fadal, H. O.:		Infection-----	³ 1551
Nembutal Capsules and sodium		Kurex Hillgrove Laboratories,	
phenobarbital capsules-----	1561	Inc.:	
Fadal's Square Drug Store. <i>See</i>		Kurex-----	¹ 1578
Fadal, H. O.		Lloyd Brothers Pharmacists, Inc.:	
Fernel, Dr. J. P.:		Lobelia herb-----	1568
Thymus Arthritis Treatment,		Loveless, T.:	
Liniodol, and Breasts of		spirits of camphor, isopropyl	
Youth Capsules-----	¹ 1560	rubbing alcohol compound,	
First Texas Chemical Manufac-		camphorated oil, sweet oil,	
turing Co.:		and solution of boric acid--	1574
Amylofene and ephedrine cap-		Loveless Pharmacal Co. <i>See</i>	
sules-----	¹ 1570	Loveless, T.	
Golden, T. T.:		McCormick & Co.:	
Bullock's System Self-Treat-		balsam copaiba-----	1564
ment for Sinus and Cat-		McCormick Sales Co.:	
arrhal Infection-----	³ 1551	balsam copaiba-----	1564
Gotham Sales Co., Inc.:		McJohn Cosmetic Co.:	
absorbent cotton-----	1575	Presto for Blackheads-----	1593
Griffin Grocery Co.:		Miracle Products Co.:	
"666"-----	1587	Miracle Aid for Wrinkles, Mira-	
Heron, N. C.:		cle Cream (Miracle Slender-	
Heron's Constipation Remedy		izing Cream), and Miracle	
and Liver Regulator and		Bath-----	1592
Heron's Pure Eucalyptus		Monticello Drug Co.:	
Oil-----	¹ 1563	"666"-----	1586, 1587
Heron, N. C., Co. <i>See</i> Heron,		New Aseptic Laboratories, Inc.:	
N. C.		absorbent cotton-----	1575
Hidden, E. S.:		Nu-Basic Product Co.:	
Lax Thyroid Tablets-----	1555	Pso-Ridisal-----	1566
Hillgrove, R. F.:		Nyal Co.:	
Kurex-----	¹ 1578	Astring-O-Sol-----	1594
Howerton, Dr. T. J.:		Oxford Products, Inc.:	
Bullock's System Self-Treat-		vitamin C tablets-----	1589
ment for Sinus and Catarrhal		Parke, Davis & Co.:	
Infection-----	³ 1551	crude drugs-----	1569
		Penick, S. B., & Co.:	
		wild cherry bark-----	1567
		Perl Products Co.:	
		Nokor-----	1591

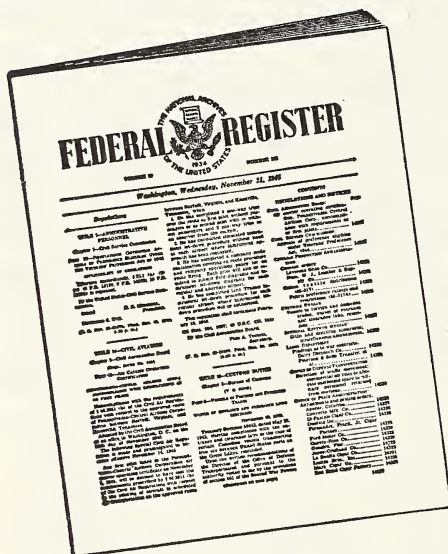
¹ Prosecution contested.² Seizure contested. Contains opinions of the courts.³ Permanent injunction issued.

	N. J. No.		N. J. No.
Phoenix Preparations:		Skelly, Eunice:	
Munyon's Paw Paw Tonic-----	1581	Contour-Molde "Face Lifting"	
Pratt Food Co.:		Bandage -----	1583
Pratt's Poultry Regulator, Animal Regulator, and Poultry Inhalant -----	1597	Skelly, Eunice, House of Youth. See Skelly, Eunice.	
Professional Drugs, Inc.:		Spangler, Henry:	
Novalene Tablets -----	1600	Bullock's System Self-Treatment for Sinus and Catarrhal Infection -----	³ 1551
Rawleigh, W. T., Co.:		Stanley's Drug Store. See Sikoparija, S. S.	
Rawleigh's Milk of Magnesia Tablets, Castoria, Ru-Mex-Ol Compound, Milk of Magnesia, Tonic Compound, Septo Powder for Poultry, and Iodized Poultry Powder -----	1590	Sulfa Products Co.:	
Russell, I. D., Co.:		Pso-Ridisal -----	1565
Russell's Korum and Russell's Spray Inhalant -----	1596	Todd, J. E., Inc.:	
Sikoparija, Mrs. Stanley. See Sikoparija, S. S.		Todd's Capsules -----	1580
Sikoparija, S. S.:		Universal Drug Products, Inc.:	
Stanley's Stomach Powder, Prescription 1-NN-1 Nerve Tablets, Prescription 1-RR-7, External No. 1, Prescription 1-H-7, and Prescription Medicine 1-B-7 -----	¹ 1553	Yuk-Air Compound -----	1557
Prescription 1-H-7, Tonic 1-X-1, Red Blood Purifier, and Prescription 1-VV-1 -----	¹ 1559	Weihe, W. P.:	
Prescription 1-VV-1, and Extract of Cod Liver -----	¹ 1579	Kurex -----	¹ 1578
		Wonder Chemical Co.:	
		Wonder Poultry Tonic and Morehog -----	1598
		Wyeth, John, & Brother, Inc.:	
		thiamine hydrochloride -----	1573
		Wynne, C. P.:	
		Munyon's Paw Paw Tonic -----	1581
		Zedd, Maxwell:	
		N. M. Tablets, C. C. Pills, and N. K. Tablets -----	1556
		Zedd's Cut Rate Drug Stores. See Zedd, Maxwell.	
		Ziegler Pharmacal Co.:	
		Pancrezyme Tablets and Obeto Ampuls -----	1582

¹ Prosecution contested.³ Permanent injunction issued.

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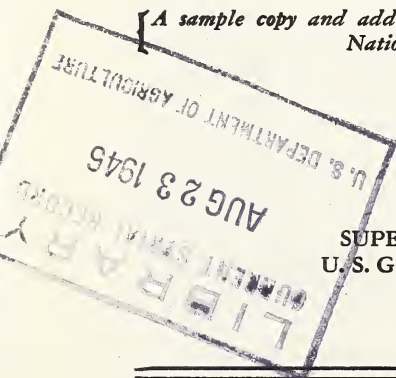


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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1601-1650

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., June 4, 1946.

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1601. Misbranding of Munyon's Remedy for Round Worms and Munyon's Improved Paw-Paw Pills (also known as Munyon's Laxative Pills). U. S. v. Penn Drug & Supply Co. Plea of guilty. Fine, \$400. (F. D. C. No. 15530. Sample Nos. 42281-F, 77721-F.)

INFORMATION FILED: June 5, 1945, Middle District of Pennsylvania, against the Penn Drug & Supply Co., a corporation, Scranton, Pa.

ALLEGED SHIPMENT: On or about November 12, 1943, and January 3, 1944, from the State of Pennsylvania into the States of Delaware and Indiana.

PRODUCT: Analyses disclosed that the *Munyon's Remedy for Round Worms* consisted essentially of sugar, with a small proportion of mineral matter; and that the *Munyon's Paw-Paw Pills* consisted essentially of aloin and laxative drugs.

LABEL, IN PART: "Munyon's Remedy for Round Worms [or "Munyon's Improved Paw-Paw Pills—Cathartic"] * * * Munyon Remedy Corp. [or "Co."] Scranton, Pa."

NATURE OF CHARGE: *Munyon's Remedy for Round Worms*, misbranding, Section 502 (a), the label statement, "Munyon's Remedy for Round Worms Prepared for expelling worms and as a tonic for weak children," was false and misleading since the article would not be efficacious in the cure, mitigation, treatment, and prevention of roundworms; it would not be efficacious for expelling roundworms; and it would not be an effective tonic for weak children; Section 502 (b) (2), the labels on the vials containing the article bore no statement of the quantity of the contents of the vials; and, Section 502 (e) (2), the labels

*For failure to comply with the labeling requirements of an official compendium, see No. 1624; presence of a noncertified coal-tar color, No. 1633; deceptive packaging, No. 1648.

failed to bear the common or usual name of each active ingredient of the article.

Munyon's Improved Paw-Paw Pills, misbranding, Section 502 (a), the label statements, "For * * * Indigestion, Headaches and Similar Disorders" and "for * * * Indigestion, Liver Ailments, Headaches and Similar Disorders," were false and misleading, since the article would not be efficacious in the cure, mitigation, treatment, and prevention of indigestion, liver ailments, headaches, and similar disorders; Section 502 (b) (2), the labels on the vials containing the article bore no statement of the quantity of the contents; Section 502 (e) (2), the labels failed to bear the common or usual name of each active ingredient of the article; and, Section 502 (f) (2), the article was a laxative and its labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that continued and habitual use of the article might result in dependence on laxatives to move the bowels.

DISPOSITION: June 12, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$200 on each count, a total fine of \$400.

1602. Misbranding of George's Rx 205 Tablets and Pepotabs Tablets. U. S. v. George F. Hauptman (Market Drug Co.). Plea of nolo contendere. Fine, \$250. (F. D. C. No. 15505. Sample Nos. 50684-F, 50857-F.)

INFORMATION FILED: April 26, 1945, Eastern District of Pennsylvania, against George F. Hauptman, trading as the Market Drug Company, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about January 8 and June 10, 1944, from the State of Pennsylvania into the State of New Jersey.

PRODUCT: Analyses disclosed that the *George's Rx 205 Tablets* consisted of red tablets containing plant material and small proportions of strychnine and phosphorus compounds and white tablets containing thiamine chloride; and that the *Pepotabs Tablets* consisted of brown tablets and white tablets, the brown tablets containing a bitter resin, such as damiana, and small proportions of strychnine and phosphorus compounds, and the white tablets containing thiamine chloride.

NATURE OF CHARGE: *George's Rx 205 Tablets*, misbranding, Section 502 (a), the label statement, "Recommended * * * for persons over 35 years of Age," created the misleading impression that the red and white tablets, when used in conjunction with each other, would be of especial value to persons over 35 years of age, i. e., that they would rejuvenate persons over 35 years of age. Further misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that orchic substance is therapeutically inert when taken orally, as directed in the labeling of the article, which fact was material in the light of the label representation, "Red Tablets Contain: * * * Avenin Orchic Substance * * * Directions: One Red Tablet and one White Tablet, with half glass of water, twice a day."

Pepotabs Tablets, misbranding, Section 502 (a), the name "Pepotabs" created the misleading impression that the article possessed the health-giving and rejuvenating properties implied in the expression "Pep"; and the label statement, "Recommended * * * for persons over 35 years of Age," created the misleading impression that the brown and white tablets, when used in conjunction with each other, would be of special value to persons over 35 years of age, i. e., that they would rejuvenate persons over 35 years of age. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings since the brown tablets contained strychnine and the labeling failed to warn that frequent or continued use of the article was to be avoided and that use of the article by children and elderly persons might be especially dangerous.

DISPOSITION: June 20, 1945. A plea of nolo contendere having been entered, the court imposed a fine of \$250.

1603. Misbranding of Prentils. U. S. v. 705,792 Tablets, 13,680 Tablets, and 36 Cartons of Prentils. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14605. Sample Nos. 76092-F, 76093-F, 76099-F, 76100-F.)

LABEL FILED: December 4, 1944, Northern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of October 22, 1943, and September 12, 1944, by the Ivers-Lee Co., from Newark, N. J.

PRODUCT: *Prentils*, 705,792 tablets in 46 original shipping cartons, 13,680 tablets in 840 cartons containing 12 tablets each, and 36 cartons, each containing 100 tablets, at Utica, N. Y. The product was shipped unlabeled except for the name and address of the shipper and a statement of the quantity of the contents; and there was no agreement between the shipper and the consignee for the labeling of the product by the consignee.

Examination showed that each tablet of the article consisted essentially of $2\frac{1}{2}$ grains of acetphenetidin, $2\frac{1}{2}$ grains of salicylic acid, and caffeine.

NATURE OF CHARGE: Misbranding, Section 502 (e), the label of the article failed to bear the common or usual name of each ingredient, including the name and quantity or proportion of acetphenetidin; Section 502 (f) (1), it failed to bear adequate directions for use; and, Section 502 (f) (2), it failed to warn that frequent or continued use of a drug containing acetphenetidin may be dangerous, causing serious blood disturbances.

DISPOSITION: June 13, 1945. The Prentil Corporation, Utica, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1604. Adulteration of Indian rhubarb root. U. S. v. 19 Bags of Indian Rhubarb Root. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15634. Sample No. 22435-H.)

LIBEL FILED: March 16, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about May 22, 1944, by the Smith Crude Drug and Spice Co., New York, N. Y.

PRODUCT: 19 bags, each containing about 85 pounds, of *Indian rhubarb root* at Peoria, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insect-eaten pieces, insect fragments, and insect excreta.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1605. Adulteration of stramonium leaves and calamus. U. S. v. 12 Bags of Stramonium Leaves and 7 Bags of Calamus. Consent decrees of condemnation. Stramonium leaves ordered released under bond; calamus ordered destroyed. (F. D. C. Nos. 14872, 15366. Sample Nos. 98811-F, 22410-H.)

LIBELS FILED: January 2 and March 12, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about July 9, 1941, and May 11, 1944, by the St. Louis Commission Co., from St. Louis, Mo.

PRODUCT: 12 150-pound bags of *stramonium leaves* and 7 65-pound bags of *calamus* at Peoria, Ill. Examination showed that the *stramonium leaves* were contaminated with insects, insect fragments, and rodent hairs, whereas the United States Pharmacopoeia provides that "Vegetable * * * drugs are to be substantially free from insects or other animal life, extraneous animal material, or animal excreta." The *calamus* was contaminated with insect larvae and excreta.

NATURE OF CHARGE: *Calamus*, adulteration, Section 501 (a) (2), the article had been prepared, packed, or held under insanitary conditions whereby it had become contaminated with filth.

Stramonium leaves, adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of decrees, judgments of condemnation were entered and the *stramonium leaves* were ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. The *calamus* was ordered destroyed.

1606. Adulteration of scammony root. U. S. v. 125 Bags of Scammony Root. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15366. Sample No. 22439-H.)

LIBEL FILED: March 12, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about November 19, 1942, by Belarmino Gutierrez, from Vera Cruz, Mex.

PRODUCT: 125 90-pound bags of *scammony root* at Peoria, Ill. Examination showed that the product was contaminated with insects and insect fragments.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the article had been prepared, packed, or held under insanitary conditions whereby it had become contaminated with filth.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1607. Adulteration of American wormseed. U. S. v. 18 Bags of American Wormseed. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15366. Sample No. 22405-H.)

LIBEL FILED: March 12, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about December 27, 1944, by Samuel Baer, Sr., and Sons, from Wilmington, N. C.

PRODUCT: 18 125-pound bags of *American wormseed* at Peoria, Ill. Examination showed that the product was contaminated with insect larvae.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the article had been prepared, packed, or held under insanitary conditions whereby it had become contaminated with filth.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1608. Adulteration of wormwood. U. S. v. 32 Bags of Wormwood. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15366. Sample No. 22404-H.)

LIBEL FILED: March 12, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about February 1, 1943, by Rodolfo L. Flores y Cia., from Laredo, Tex.

PRODUCT: 32 50-pound bags of *wormwood* at Peoria, Ill. Examination showed that the product was contaminated with larvae and insects.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the product had been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS¹

1609. Adulteration of liver solution. U. S. v. 182 Vials and 21 Vials of Liver Solution. Default decrees of condemnation and destruction. (F. D. C. Nos. 14676, 15347. Sample Nos. 13678-F, 11511-H.)

LIBELS FILED: November 30, 1944, and March 3, 1945, Southern District of California and District of Massachusetts.

ALLEGED SHIPMENT: On or about September 15, 1944, and January 15, 1945, by the Drug Products Co., from Long Island City, N. Y.

PRODUCT: 182 vials of *liver solution* at Los Angeles, Calif., and 21 vials of *liver solution* at Hingham, Mass.

¹ See also No. 1605.

LABEL, IN PART: "10 cc Size * * * Hyposols Liver Solution U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be liver injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

DISPOSITION: December 20, 1944, and April 9, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1610. Adulteration of isotonic solution of three chlorides and dextrose in isotonic solution of sodium chloride. U. S. v. 26 Flasks of Isotonic Solution of Three Chlorides and 38 Flasks of Dextrose in Isotonic Solution of Sodium Chloride. Default decree of condemnation and destruction. (F. D. C. No. 15282. Sample Nos. 6385-H, 6386-H.)

LIBEL FILED: February 16, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about October 16 and 25, 1944, by Readyflask, Inc., from Lakewood, Ohio.

PRODUCT: 26 1,000-cc. flasks of *isotonic solution of three chlorides* and 38 1,000-cc. flasks of *dextrose in isotonic solution of sodium chloride*, at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "No. 3—Sterile Isotonic Solution of Three Chlorides for Parenteral Use" and "Dextrose and Sodium Chloride Injection," drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the official standards since they were contaminated with undissolved material.

DISPOSITION: May 17, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1611. Adulteration of water for injection and solution of sodium citrate. U. S. v. 31 Packages of Water for Injection and 188 Ampuls and 476 Ampuls of Solution of Sodium Citrate. Decrees of condemnation and destruction. (F. D. C. Nos. 15359, 15633, 16209. Sample Nos. 3820-H, 24148-H, 24274-H.)

LIBELS FILED: Between March 8 and May 24, 1945, District of New Jersey, Eastern District of Louisiana, and Northern District of Texas; amended libel filed March 20, 1945, Eastern District of Louisiana.

ALLEGED SHIPMENT: Between the approximate dates of June 13, 1944, and February 7, 1945, by Sharp and Dohme, Inc., from Philadelphia, Pa.

PRODUCT: 31 packages, each containing 25 ampuls, of *water for injection* at Trenton, N. J., and 188 ampuls and 476 ampuls of *solution of sodium citrate* at New Orleans, La., and Dallas, Tex., respectively.

LABEL, IN PART: "Water for Injection U. S. P. XII," or "50-cc. Size Ampul Sterile Anticoagulant Solution of Sodium Citrate U. S. P. XII 2½ Per Cent For Parenteral Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the official standards in that they were contaminated with undissolved material.

DISPOSITION: Between May 12 and June 25, 1945. The sole intervener for the Louisiana lot having consented to the entry of a decree, and no claimant having appeared for the other lots, judgments of condemnation were entered and the products were ordered destroyed.

1612. Adulteration of dextrose in isotonic solution of sodium chloride. U. S. v. 33 Cartons and 72 Flasks of Dextrose in Isotonic Solution of Sodium Chloride. Default decrees of destruction. (F. D. C. Nos. 15361 to 15363, incl. Sample Nos. 27422-H, 29313-H, 29314-H.)

LIBELS FILED: March 26 and April 20, 1945, District of Utah and Western District of Washington.

ALLEGED SHIPMENT: On or about February 7, 1945, by the Cutter Laboratories, from Berkeley, Calif.

PRODUCT: 33 cartons, each containing 6 flasks, of *dextrose in isotonic solution of sodium chloride* at Seattle, Wash., and 72 flasks of the same product at Salt Lake City, Utah.

LABEL, IN PART: (Flask label) "Saftiflask * * * Dextrose 5% W/V in Isotonic Solution of Sodium Chloride"; (carton label) "A safe, sterile, pyrogen-free solution." An enclosed circular gave directions for the use of "Cutter Intravenous Solutions in Saftiflasks."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it contained undissolved material.

DISPOSITION: June 2 and September 20, 1945. No claimant having appeared, judgments were entered ordering that the Seattle lot be condemned and destroyed and that the Salt Lake City lot be destroyed.

1613. Adulteration and misbranding of estrogenic material in oil. U. S. v. 470 Ampuls of Estrogenic Material in Oil. Default decree of condemnation and destruction. (F. D. C. No. 15806. Sample No. 4117-H.)

LABEL FILED: On or about April 14, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about March 9, 1945, from Philadelphia, Pa., by the Associated Ross-Good Laboratories.

PRODUCT: 470 ampuls of *estrogenic material in oil* at Penns Grove, N. J.

LABEL, IN PART: "Estrogenic Material in oil * * * This Estrogenic Material contains—Estrodial, Estrone and other Estrogenic factors of Pregnant Mares Urine."

NATURE OF CHARGE: Adulteration, Section 501 (d), an oil solution of estrogenic material consisting almost entirely of estradiol had been substituted for an oil solution of estrogenic material containing estradiol, estrone, and other estrogenic factors as they occur in pregnant mares' urine.

Misbranding, Section 502 (a), the label statement, "This Estrogenic Material contains—Estradiol, Estrone and other Estrogenic factors of Pregnant Mares Urine," was misleading since it represented and implied that the estrogenic material in the article was estrogenic material as it occurs naturally in pregnant mares' urine, whereas it was not.

DISPOSITION: May 25, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1614. Adulteration and misbranding of Duchex. U. S. v. 22 Dozen Packages of Duchex. Default decree of condemnation and destruction. (F. D. C. No. 15296. Sample No. 13808-H.)

LABEL FILED: On or about February 22, 1945, Northern District of Ohio.

ALLEGED SHIPMENT: On or about December 21, 1944, by Hachmeister, Inc., from Pittsburgh, Pa.

PRODUCT: 22 dozen packages of *Duchex* at Cleveland, Ohio. Examination of a sample showed that the article was not germicidal when used in accordance with the directions appearing on its label.

LABEL, IN PART: "Duchex For Feminine Hygiene."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from and its quality fell below that which it purported and was represented to possess, namely, germicidal.

Misbranding, Section 502 (a), the following labeling statements were false and misleading since the article was not germicidal: (Carton) "Duchex represents the most advanced scientific preparation for Feminine and Marriage Hygiene. * * * what germicide is best * * * Duchex is * * * very effective * * * killing contacted germ life. * * * Its basic germicidal ingredient is Sodium Para Toluene Sulphon Chloramide which is accepted by the American Medical Association. Bacteriological Tests prove this ingredient 54 times more powerful and 288 times faster than any Phenol solution harmless to body tissues. * * * The ideal personal germicide * * * Duchex is powerful and quick acting * * * for * * * killing germ life it contacts. * * * with no unpleasant disinfectant odor. * * * Modern Physicians and experienced Nurses recommend medicated douching at least three times weekly for * * * good health"; (envelope) "Duchex is * * * very, very effective for * * * killing contacted germ life. Its germicidal ingredient, (Sodium Para Toluene Sulphon Chloramide) is accepted by the American Medical Association."

DISPOSITION: May 28, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1615. Adulteration and misbranding of Special S. C. Red Tablets. U. S. v. 1 Drum of Special S. C. Red Tablets. Default decree of destruction. (F. D. C. No. 15970. Sample No. 18554-H.)

LABEL FILED: April 28, 1945, District of Minnesota.

ALLEGED SHIPMENT: On or about August 2, 1944, by Charles H. Dietz, Inc., from St. Louis, Mo.

PRODUCT: 1 drum containing approximately 55,000 *Special S. C. Red Tablets* at St. Paul, Minn. The product contained approximately 20 percent less arsenious acid and strychnine sulfate than was declared on the label.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet contained materially less arsenious acid and strychnine sulfate than was declared on the label.

Misbranding, Section 502 (a), the label statement, "Each C. T. Contains Arsenious Acid 1/50 gr. Strychnine Sulphate 1/60 gr.," was false and misleading

DISPOSITION: June 13, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1616. Adulteration and misbranding of Hi-Test Vegetable Compound with Thiamin Chloride. U. S. v. 160 Cartons of Vegetable Compound with Thiamin Chloride. Default decree of condemnation and destruction. (F. D. C. No. 15976. Sample No. 22454-H.)

LABEL FILED: April 28, 1945, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about October 25, 1944, by the Allied Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 160 cartons, each containing 1 bottle, of *Hi-Test Vegetable Compound with Thiamin Chloride* at St. Louis, Mo. Examination showed that the product contained no demonstrable amount of vitamin B₁.

LABEL, IN PART: "Hi-Test Vegetable Compound with Thiamin Chloride B₁ Contents 1 Pint"

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements, "Vegetable Compound with Thiamin Chloride B-1 * * * Active Ingredients Crystalline Vitamin B-1" and "Each ounce contains 250 units of B-1. The daily average dose of 3 tablespoonsful supply the full daily requirement of B-1," were false and misleading as applied to the article, which contained no demonstrable amount of vitamin B₁.

DISPOSITION: May 21, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1617. Adulteration and misbranding of thiamine hydrochloride tablets. U. S. v. 1 Drum of Thiamine Hydrochloride Tablets. Default decree of forfeiture and destruction. (F. D. C. No. 15964. Sample No. 13035-H.)

LABEL FILED: April 26, 1945, Southern District of Indiana.

ALLEGED SHIPMENT: On or about December 2, 1943, by Charles H. Dietz, Inc., from St. Louis, Mo.

PRODUCT: 1 drum containing 25,000 *thiamine hydrochloride tablets* at Indianapolis, Ind.

LABEL, IN PART: "Compressed Tablet Thiamin Hydrochloride."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the standard set forth therein since it contained less than 95 percent of the amount of thiamine hydrochloride declared on its label.

Misbranding, Section 502 (a), the label statements, "Thiamin Hydrochloride 1 MGM. Each CT contains Thiamin HCL 1 MGM. Equivalent to 333 U. S. P. Units B₁. Dose for Adults: One tablet repeated only as prescribed. The minimum adult daily requirements for a day is 333 U. S. P. Units," were false and misleading as applied to the article, which contained less than the declared amount of thiamine hydrochloride.

DISPOSITION: June 6, 1945. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1618. Adulteration of ginger root. U. S. v. 21 Bags of Ginger Root. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14871. Sample No. 98809-F.)

LIBEL FILED: January 2, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about July 20, 1944, by S. H. Ewing, Ltd., from Montreal, Can.

PRODUCT: 21 100-pound bags of *ginger root* at Peoria, Ill. Examination disclosed that the article was contaminated with insect excreta and live insects. The United States Pharmacopoeia provides that "Vegetable * * * drugs are to be substantially free from insects or other animal life, extraneous animal material, or animal excreta."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1619. Adulteration of wild cherry bark. U. S. v. 15 Bags of Wild Cherry Bark. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14873. Sample No. 98812-F.)

LIBEL FILED: January 2, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about May 11, 1944, by the Greer Drug Co., from Lenoir, N. C.

PRODUCT: 15 130-pound bags of *wild cherry bark* at Peoria, Ill. Examination showed that the product was contaminated with insects, insect fragments, rodent hairs, and feather fragments. The United States Pharmacopoeia provides that "Vegetable * * * drugs are to be substantially free from insects or other animal life, extraneous animal material, or animal excreta."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration.

1620. Adulteration of valerian root. U. S. v. 36 Bags of Valerian Root. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15843. Sample No. 22428-H.)

LIBEL FILED: April 3, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about October 5, 1944, from New York, N. Y., by the Kachurin Drug Co.

PRODUCT: 36 40-pound bags of *valerian root* at Peoria, Ill. Examination showed that the product consisted of Indian valerian mixed with approximately 10 percent of foreign organic matter, whereas the National Formulary provides that valerian shall contain not more than 4 percent of foreign organic matter.

LABEL, IN PART: "Valerian Root Ind."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its purity fell below the official standard.

DISPOSITION: May 24, 1945. Allaire, Woodward and Co., Peoria, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration.

1621. Adulteration of dandelion root. U. S. v. 14 Bags of Dandelion Root (and 2 other seizure actions against dandelion root). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 15796 to 15798, incl. Sample Nos. 5949-H, 5950-H.)

LIBELS FILED: April 6, 1945, Eastern District of New York.

ALLEGED SHIPMENT: On or about December 23, 1940, and June 18, 1941, from Argentina and Russia.

PRODUCT: 67 bags and 6 barrels of *dandelion root* at Brooklyn, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard, which provides that vegetable drugs are to be as free as practicable from molds, insects, or other animal life, and animal excreta, and shall show no evidence of deterioration. The article was badly worm-bored and contained live and dead insects, and insect excreta, and a portion was contaminated with mold.

DISPOSITION: June 27, 1945. The Kachurin Drug Co., New York, N. Y., claimant, having admitted the allegations of the libels, and the cases having been consolidated, judgment of condemnation was entered and the product was ordered released under bond, conditioned that it be fumigated and cleaned and the unfit portion destroyed, under the supervision of the Food and Drug Administration.

1622. Adulteration of lubricating jelly. U. S. v. 11 Dozen Tubes and 9½ Dozen Tubes of Lubricating Jelly. Default decrees of condemnation and destruction. (F. D. C. Nos. 15674, 15743. Sample Nos. 9325-H, 11444-H.)

LIBELS FILED: On or about March 24, 1945, Northern District of New York and District of Connecticut.

ALLEGED SHIPMENT: On or about February 6 and 7, 1945, by the McNeil Laboratories, Philadelphia, Pa.

PRODUCT: 11 dozen tubes of *lubricating jelly* at Ithaca, N. Y., and 9½ dozen tubes of the same product at Norwich, Conn. Examination showed that the article was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Tube Lubricant A Sterile * * * Jelly."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess.

DISPOSITION: May 7 and 28, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1623. Adulteration and misbranding of absorbent cotton. U. S. v. 94 Cartons of Absorbent Cotton. Default decree providing for destruction of the product or its delivery to a charitable institution. (F. D. C. No. 15460. Sample No. 18930-H.)

LIBEL FILED: March 5, 1945, District of Minnesota.

ALLEGED SHIPMENT: On or about January 12, 1945, by the American White Cross Laboratories, Inc., Cape Girardeau, Mo.

PRODUCT: 94 1-pound cartons of *absorbent cotton* at Minneapolis, Minn. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "U. S. P. Physicians and Surgeons Absorbent Cotton."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard in that it was not sterile.

Misbranding, Section 502 (a), the statements on the cartons, "U. S. P. Physicians and Surgeons Absorbent Cotton Sterilized after Packaging * * * Surgical Quality Hospital Quality * * * Manufactured and packed under * * * sanitary conditions. Sterilized after packaging," were false and misleading as applied to the article, which was not sterile.

DISPOSITION: May 15, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed or delivered to a charitable institution.

1624. Adulteration and misbranding of adhesive compresses and adhesive bandages. U. S. v. 30 Cases of Adhesive Compresses (and 2 seizure actions against adhesive bandages). Default decrees of condemnation and destruction. (F. D. C. Nos. 14649, 14801, 15060. Sample Nos. 54670-F, 79769-F, 79770-F, 88677-F.)

LIBELS FILED: December 15, 1944, and January 4 and 17, 1945, Northern District of West Virginia, Northern District of Illinois, and District of Maine.

ALLEGED SHIPMENT: On or about August 18 and 25 and December 1, 1944, by the A. E. Halperin Co., Inc., from Boston, Mass.

PRODUCT: 30 cases of *adhesive compresses* at Lost Creek, W. Va., 138 boxes of *adhesive bandages* at Elwood, Ill., and 14 gross folders of *adhesive bandages* at Portland, Maine.

LABEL, IN PART: "Halco Handy Adhesive Bandage," "Adhesive Compress Unit No. 3," or "Uniplast Instant Bandage * * * Uniplast Surgical Dressing Co., Boston, Mass."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be "Adhesive Absorbent Gauze" and "Adhesive Absorbent Compress," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, and their quality and purity fell below the official standard since they were not sterile, as required by the Pharmacopoeia.

Uniplast Instant Bandage, misbranding, Section 502 (a), the statements on the folder label, "for cuts, abrasions minor wounds * * * apply gauze to wound," were misleading since they represented and suggested that the article was suitable for the uses recommended, whereas it was not suitable for those uses since it was not sterile. Further misbranding, Section 502 (c), the label of the article failed to bear on the retail folder a statement of the quantity of the contents in terms of numerical count.

Shipment labeled "Adhesive Compress Unit No. 3," misbranding, Section 502 (g), the article was not labeled as prescribed in the United States Pharmacopoeia since some packages had been treated with a bacteriostatic agent and the label failed to bear the name of that agent.

DISPOSITION: January 5, February 2, and March 10, 1945. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1625. Adulteration of Gauztex. U. S. v. 16 Dozen Packages of Gauztex (and 3 other seizure actions against Gauztex). Default decrees of condemnation and destruction. (F. D. C. Nos. 15812, 15901, 15993, 15994. Sample Nos. 6659-H, 13442-H, 13843-H, 23731-H.)

LIBELS FILED: Between April 11 and May 5, 1945, District of Connecticut, Southern District of Texas, and Northern District of Ohio.

ALLEGED SHIPMENT: Between February 16 and April 2, 1945, by General Bandages, Inc., from Chicago, Ill.

PRODUCT: *Gauztex*, 16 dozen packages at New Haven, Conn., 4 cartons at Houston, Tex., 6 packages at Toledo, Ohio, and 18 dozen packages at Cleveland, Ohio.

LABEL, IN PART: "Gauztex * * * Medicated with Mercuric Chloride Antiseptic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was a bandage and was not sterile.

DISPOSITION: Between May 26 and June 27, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1626. Adulteration and misbranding of adhesive strips. U. S. v. 10 Gross Cartons of Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 15942. Sample No. 10038-H.)

LIBEL FILED: April 19, 1945, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 24, 1944, by the Hampton Manufacturing Co., from Carlstadt, N. J.

PRODUCT: 10 gross cartons of *adhesive strips* at Pittsburgh, Pa.

LABEL, IN PART: "Blue Cross Sterilized Adhesive Strips Sulfathiazole pad."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: May 24, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1627. Adulteration of treated adhesive strips. U. S. v. 40 Gross Packages of Treated Strips. Default decree of condemnation and destruction. (F. D. C. No. 15957. Sample No. 10037-H.)

LABEL FILED: April 24, 1945, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 12, 1945, by C. I. Lee and Co., Inc., from Yonkers, N. Y.

PRODUCT: 40 gross packages of *treated strips* at Pittsburgh, Pa. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Sanette S Treated Strips Sanette Mfg. Co. New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

DISPOSITION: May 24, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1628. Adulteration of prophylactics. U. S. v. 175 Dozen Prophylactics. Default decree of destruction. (F. D. C. No. 15482. Sample No. 20601-H.)

LABEL FILED: On or about March 13, 1945, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 26, 1945, by the Aronab Products Co., from San Francisco, Calif.

PRODUCT: 175 dozen *prophylactics* made from animal membranes and located at North Kansas City, Mo. Examination showed that of 60 samples, 6.7 percent were defective in that they contained holes.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported to possess.

DISPOSITION: April 26, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1629. Adulteration of prophylactics. U. S. v. 200 Gross of Prophylactics. Default decree of destruction. (F. D. C. No. 14787. Sample No. 87679-F.)

LABEL FILED: December 18, 1944, District of Minnesota.

ALLEGED SHIPMENT: On or about October 4 and November 15, 1944, by Hardy Newman and Co., from Chicago, Ill.

PRODUCT: 200 gross of *prophylactics* at Minneapolis, Minn. Examination of samples showed that the product was defective in that it contained holes.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

DISPOSITION: May 2, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1630. Adulteration and misbranding of prophylactics. U. S. v. 16¼ Gross and 120 Gross of Prophylactics. Default decrees of condemnation and destruction. (F. D. C. Nos. 14878, 15814. Sample Nos. 79950-F, 22331-H.)

LABELS FILED: December 28, 1944, and March 29, 1945, District of Maryland and Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about July 18, 1944, and January 18, 1945, by W. H. Reed and Co., from Atlanta, Ga.

PRODUCT: 16¼ gross of *prophylactics* at Camp Ritchie, Md., and 120 gross of *prophylactics* at Little Rock, Ark. Examination of the product showed the presence of perforations or holes.

LABEL, IN PART: "Golden Pheasant," or "Pan Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the statements in the labeling of one lot, "Prophylactics," and of the other lot, "Tested Fine Quality" and "Prophylactics Carefully Tested," were false and misleading as applied to an article containing holes.

DISPOSITION: February 8 and May 1, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1631. Adulteration and misbranding of prophylactics. U. S. v. 118 Gross, etc., of Prophylactics (and 2 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 15616, 15653, 16937. Sample Nos. 16602-H to 16604-H, incl., 16606-H, 16608-H, 16609-H, 18375-H, 18377-H.)

LIBELS FILED: Between March 19 and July 30, 1945, Northern District of Illinois and District of Minnesota.

ALLEGED SHIPMENT: Between the approximate dates of December 14, 1944, and July 6, 1945, by the Dean Rubber Manufacturing Co., from North Kansas City, Mo.

PRODUCT: 166½ gross of *prophylactics* at Chicago, Ill., and 48 gross of *prophylactics* at Minneapolis, Minn. Examination of samples disclosed that the product was defective in that it contained holes.

LABEL, IN PART: "Dean's Peacocks Reservoir Ends," "Genuine Peacocks Dean's Reservoir End," "Sekurity Prophylactics," "Parisians," or "Ultrex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to an article containing holes: "tested * * * for your protection. * * * An aid in preventing venereal diseases"; "Guaranteed 2 years against deterioration. Each and Every Peacock Device is 'Scientifically Tested' * * * An aid in preventing venereal disease"; "Sekurity Prophylactics Sekurity's are tested * * * for your protection. * * * An aid in preventing venereal diseases"; "An aid in preventing Venereal disease. Guaranteed for 2 years against deterioration. Every individual Parisian is carefully selected and tested"; and "For your Health's Sake * * * selected prophylactic * * * a reliable safeguard for your health."

DISPOSITION: December 14, 1945, and January 28, 1946. No claimant appearing when the libel proceedings came up for final decision, judgments of condemnation were entered and the products were ordered destroyed.

1632. Adulteration and misbranding of prophylactics. U. S. v. 16¼ Gross and 111½ Gross of Prophylactics. Default decrees of condemnation and destruction. (F. D. C. Nos. 15655, 15989. Sample Nos. 25420-H, 26447-H.)

LIBELS FILED: On or about March 23 and May 3, 1945, District of Colorado and District of Utah.

ALLEGED SHIPMENT: Between the approximate dates of December 28, 1944, and March 8, 1945, from Akron, Ohio, by the Akron Drug and Sundries Co.

PRODUCT: 16¼ gross of *prophylactics* at Denver, Colo., and 111½ gross of *prophylactics* at Salt Lake City, Utah. Examination of samples disclosed that the article was defective in that it contained holes.

LABEL, IN PART: "Derbies Manufactured for Jay Dee Drug Co., Chicago, Ill. By the Killian Manufacturing Co. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement, "for the prevention of Disease," was false and misleading as applied to an article containing holes.

DISPOSITION: April 7 and July 28, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1633. Adulteration and misbranding of Burma Foot Cream. U. S. v. Sexton Drug Store (The Belmont Co.). Pica of guilty. Fine, \$100. (F. D. C. No. 14295. Sample No. 68109-F.)

INFORMATION FILED: May 2, 1945, District of Massachusetts, against the Sexton Drug Store, a corporation trading as the Belmont Co., at Springfield, Mass.

ALLEGED SHIPMENT: On or about April 14, 1944, from the State of Massachusetts into the State of Ohio.

*See also Nos. 1601, 1602, 1613-1617, 1623, 1624, 1626, 1630-1632.

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained, for purposes of coloring only, a coal-tar color, dimethylaminoazobenzene, known as **Butter Yellow** (Colour Index 19), which had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified in accordance with the regulations.

Misbranding, Section 502 (a), the label statement, "Green Food Color," was false and misleading since it represented and suggested that the article contained a color which was fit for use in coloring foods, whereas the article contained dimethylaminoazobenzene, a noncertified dye which is unfit for use in foods; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; in fact, the label bore no statement of the quantity of the contents.

DISPOSITION: July 10, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$100.

1634. Misbranding of Manna Arabian Tea. U. S. v. Charles W. Nichols. Plea of guilty. Sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 15528. Sample Nos. 61270-F, 75927-F.)

INFORMATION FILED: June 22, 1945, Southern District of Ohio, against Charles W. Nichols, Cambridge, Ohio.

ALLEGED SHIPMENT: On or about July 25 and August 16, 1944, from the State of Ohio into the States of Louisiana and West Virginia.

PRODUCT: Examination of samples showed that the product consisted of the ground leaves and stems of alfalfa.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars entitled "A Treatise on Health" and "Diabetes—its Cause and Cure," in a leaflet entitled "Directions," and in a certain testimonial sheet, enclosed in the packages containing the article, were false and misleading since they represented and suggested that the article would be efficacious to feed the liver first and put it back to work; that it would cause the proper amount of bile to be manufactured; that it would be efficacious to improve the general health; that it would cause acid and gas to cease; that it would purify the blood through the kidneys; that it would be efficacious in the cure, mitigation, treatment, and prevention of constipation, indigestion, ulcers of the stomach, colon, and bladder, neuritis, arthritis, rheumatism, high and low blood pressure, anemia, liver troubles, kidney ailments, excessive fat, underweight, colds, nervousness, heart trouble, colitis, and impaired sight; that use of the article would enable a person to "live to be 100 years old"; that it would be an adequate treatment for colds and flu; that it would break up colds and flu in 24 hours; that it would cure diabetes when used in conjunction with vinegar and saltpeter; that it would be efficacious to reconstruct and build up the body of the diabetic; and that use of the article would correct nutritional deficiencies and balance nutrition. The article would not be efficacious for the purposes represented.

DISPOSITION: June 27, 1945. A plea of guilty having been entered, the court suspended sentence and placed the defendant on probation for 2 years.

1635. Misbranding of Concentra. U. S. v. 120 Packages and 13 Packages of Concentra, and a number of circulars. Default decrees of condemnation and destruction. (F. D. C. Nos. 15803, 16084. Sample Nos. 13445-H, 13449-H, 14609-H.)

LABELS FILED: March 26 and May 5, 1945, Eastern District of Michigan and Northern District of Ohio.

ALLEGED SHIPMENT: Between the approximate dates of January 29 and April 2, 1945, by Jean Ferrell, Inc., from Chicago, Ill.

PRODUCT: 120 packages of *Concentra* and 5,000 circulars entitled, "Concentra. A Scientifically Compounded Formula Of Vegetables, Fruits And Roots," at Detroit, Mich., and 13 packages of the product and 50 circulars at Toledo, Ohio. Examination showed that the product consisted essentially of powdered plant material, including a laxative drug such as rhubarb root.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circulars were false and misleading since they represented and suggested that the article would supply something of nutritional value to the body, and that it would be effective in the treatment of kidney and bladder trouble, rheumatism, spastic colon, overweight, a tired and worn-out feeling, neuritis, goiter, sore and stiff joints, constipation, headaches, arthritis, bad

eyes, loss of hair, underweight, intestinal flu, diabetes, sinus trouble, bad acid conditions, and many diseases resulting from the accumulation of waste materials and toxic poisons in the system. The article, which was essentially a laxative, would not supply anything of significant nutritional value to the body, and it would not be effective for the purposes claimed.

DISPOSITION: June 4 and 6, 1945. No claimant having appeared, judgments of condemnation were entered and the product and circulars were ordered destroyed.

1636. Misbranding of Sulf Liquid Sulphur. U. S. v. 999 Cases of Sulf Liquid Sulphur. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15759. Sample No. 17506-H.)

LIBEL FILED: On or about May 11, 1945, Northern District of Illinois; amended libel filed on or about May 16, 1945.

ALLEGED SHIPMENT: On or about February 19, 1945, by the Sulco Products Corp., from Detroit, Mich.

PRODUCT: 999 cases, each containing 1 dozen bottles, of *Sulf Liquid Sulphur* at Chicago, Ill. Examination showed that the product consisted essentially of calcium sulfide, thiosulfate, and sulfate dissolved in water. This combination is ordinarily known as "Solution of Sulfurated Lime."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label, on accompanying display cards entitled "Relax with Sulf Liquid Sulphur," and in accompanying circulars entitled "Now . . . You Can Take A Mineral Bath in Your Own Home," were false and misleading since they represented and suggested that the article was liquid sulfur, or consisted of free and uncombined sulfur; that it would be effective in the relief of rheumatism, arthritis, gout, sciatica, and skin afflictions; that it would be effective to stimulate circulation, revitalize the body, insure a deep, refreshing sleep; and that it would bring into the home the benefits which may be derived from the course of treatments provided by the sanatoriums conducted at natural mineral springs. The article was not liquid sulfur; it did not consist of free and uncombined sulfur; and it was not effective for the purposes stated and implied.

Further misbranding Section 502 (e) (1), the label failed to bear the common or usual name of the article, "Solution of Sulfurated Lime."

DISPOSITION: May 18, 1945. The Sulco Products Corp., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1637. Misbranding of Dr. Charles Norten's Minerals and B Vitamins and Dr. Charles Norten's Minerals. U. S. v. 31 Bottles of Minerals and B Vitamins, 16 Bottles of Minerals, and 900 Folders. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15730. Sample Nos. 27534-H, 27535-H.)

LIBEL FILED: March 27, 1945, District of Oregon.

ALLEGED SHIPMENT: *Minerals and vitamins*, between the approximate dates of January 8 and February 6, 1945, by Colloidal Products, from Tampa, Fla.; folders, in the summer of 1944 and in January 1945, by the same firm.

PRODUCT: 17 60-capsule bottles and 14 180-capsule bottles of *Norten's Minerals and B Vitamins*, and 11 180-capsule bottles and 5 360-capsule bottles of *Norten's Minerals* at Portland, Oreg., together with 500 folders entitled "Dr. Charles Norten's Minerals Vitamins" and 400 pink and buff folders entitled "Startling Facts."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7907, in which are set forth the false and misleading statements referred to above.

DISPOSITION: May 9, 1945. G. E. Short, Portland, Oreg., claimant, having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the products be released under bond, conditioned upon the segregation and destruction of the folders.

1638. Misbranding of Vivogen. U. S. v. 173 Cases of Vivogen, and a number of booklets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15358. Sample Nos. 28319-H, 28324-H.)

LABEL FILED: March 19, 1945, Western District of Washington.

ALLEGED SHIPMENT: On or about January 26 and February 2, 1945, by the Vivogen Co., from Los Angeles, Calif.

PRODUCT: 173 cases, each containing 4 1-gallon bottles, of *Vivogen*, together with accompanying booklets entitled, "Astonishing New Discoveries about Sickness which are Beneficial to Good Health * * * Vivogen," at Seattle, Wash. Analysis showed that the product consisted of diluted lime water and contained 0.07 gram of calcium hydroxide in each 100 cc.

NATURE OF CHARGE: Misbranding, Section 502 (a), because of false and misleading statements in the accompanying booklets which represented, suggested, and implied that the article would be efficacious in removing the causes and in the treatment of throbbing headaches, colds, catarrh, sinus troubles, ringing in the ears, impaired sight, vertigo, gall bladder pains, varicose veins, itching skin, aching bones, numb scalp, chapped hands, rash, eczema, sunburn, burns, cuts or scratches, abrasions, sprains, swellings, colds in the chest or head, chronic sores, acute abdominal pains, common fevers, influenza, pneumonia, ptomaine poisoning, constipation, high blood pressure, kidney and bladder troubles, Bright's disease, diabetes mellitus, asthma, cancer, arthritis, severe stomach trouble, gallstones, liver trouble, kidney trouble, stomach ulcers, mastoids, sore throat, blood poisoning, la grippe, neuritis, catarrh, rheumatism, and tumors. The article would not be efficacious for the purposes represented, suggested, and implied.

Further misbranding, Section 502 (e) (2), the product was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: April 11, 1945. The Vivogen Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered relabeled under the supervision of the Food and Drug Administration.

1639. Misbranding of Glanzyme. U. S. v. 26 Bottles of Glanzyme. Decree of condemnation and destruction. (F. D. C. No. 15141. Sample Nos. 80955-F to 80958-F, incl.)

LABEL FILED: February 7, 1945, Western District of Oklahoma.

ALLEGED SHIPMENT: Between the approximate dates of October 1 and December 21, 1944, from Lynwood, Calif., by the Ryer Dietary Supplements Co.

PRODUCT: 9 bottles of *Glanzyme No. 1*, 6 bottles of *Glanzyme No. 2*, 9 bottles of *Glanzyme No. 3*, and 2 bottles of *Glanzyme No. 6* at Oklahoma City, Okla. The products were accompanied, when introduced into and while in interstate commerce, by a booklet entitled "Vitamin, Mineral and Glandular Therapy."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet were false and misleading since they represented and suggested (1) that the *Glanzyme No. 1* would serve as a female sex hormone supplement; that it would remedy subnormal sexual growth or development, or menstrual disturbances characterized by the absence of menstrual flow, or painful menstruation; that it would supplant the falling off of hormone flow throughout the pituitary-suprarenal-ovarian cycle in menopause; and that it would relieve the tension and discomfort caused by the upset condition attendant upon the change of life; (2) that the *Glanzyme No. 2* would be effective in the treatment of abnormal conditions attendant upon pregnancy and in the treatment of threatened abortion, or excessive menstruation (menorrhagia); (3) that the *Glanzyme No. 3* would be effective in the treatment of neurasthenia, mental apathy, and impotence; and (4) that the *Glanzyme No. 6* would be effective to supplement the adrenal glands and their functions; and that it would be effective as an aid in suprarenal deficiencies. The articles would not be efficacious for the purposes claimed.

Further misbranding, Section 502 (a), the subdesignation "Asthmazyme," appearing on the bottle label of the *Glanzyme No. 6* and in the booklet, was misleading since it represented and suggested that the *Glanzyme No. 6* would be an adequate treatment for asthma, whereas it would not be an adequate treatment for asthma.

Further misbranding, Section 502 (a), the designation "Glanzyme," appearing on the bottle labels of all the articles and in the booklet, was misleading

since the articles would not supply any glandular or enzymic activity and would have no therapeutic significance when consumed as directed in the labeling, "3 to 5 tablets daily or as directed by a Specialist," except for the content of iron in the *Glanzyme No. 2*; and the following statements on the bottle labels of the articles and in the booklet were misleading since the articles, when consumed as directed, would produce no therapeutic effect, and the listed ingredients were therefore not active except as to the ingredient, reduced iron, in the *Glanzyme No. 2*: (*Glanzyme No. 1*) "Active Ingredients Ovarian Residue 3 Gr. Whole Suprarenal 1 Gr. Anterior Pituitary ½ Gr. Kelp 1 Gr. Alfalfa 2 Gr. Papain (Papaya-Enzyme) 1 Gr."; (*Glanzyme No. 2*) "Active Ingredients Mammary 3 Gr. Placenta 2 Gr. Whole Pituitary ½ Gr. Kelp 1 Gr. Papain (Papaya-Enzyme) 1 Gr. Alfalfa 2 Gr. Reduced Iron ½ Gr. (22 Mg.)"; (*Glanzyme No. 3*) "Active Ingredients Orchic 4 Gr. Prostate 2 Gr. Whole Suprarenal 1 Gr. Anterior Pituitary ½ Gr. Kelp 1 Gr. Papain (Papaya-Enzyme) 1 Gr. Alfalfa 1 Gr."; (*Glanzyme No. 6*) "Active Ingredients Whole suprarenal 2 Gr. Papain (Papaya-Enzyme) ½ Gr. Kelp 1½ Gr. Alfalfa 4 Gr."

DISPOSITION: May 8, 1945. The sole intervener having consented to the entry of a decree, judgment of condemnation was entered and the products, together with the booklet, were ordered destroyed.

1640. Misbranding of SNJ Sulfathiazole Nasal Jelly. U. S. v. 11½ Dozen, 11¾ Dozen, and 11½ Dozen Packages of SNJ Sulfathiazole Nasal Jelly. Default decrees of condemnation and destruction. (F. D. C. Nos. 15799, 15800, 16063. Sample Nos. 6329-H, 27351-H, 27352-H.)

LIBELS FILED: April 16 and 26, 1945, District of Oregon and Eastern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of July 21, 1944, and February 12, 1945, by the S. N. J. Products Co., from Los Angeles, Calif.

PRODUCT: 23 dozen packages of *SNJ Sulfathiazole Nasal Jelly* at Portland, Oreg., and 11¾ dozen packages of the same product at Brooklyn, N. Y. Examination disclosed that the product possessed the composition stated upon its label.

LABEL, IN PART: "SNJ Sulfathiazole Nasal Jelly * * * Contains 3% Sodium Sulfathiazole and ½% Benzoate of Soda in a water soluble base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in the circular entitled, "Directions For Use," enclosed in the package, were false and misleading since they represented and suggested that the article would be an adequate treatment for the various disease conditions affecting the nose and throat; and that it would be effective in the relief and prevention of colds and sinus trouble. The article would not be an adequate treatment, and it would not be effective for the conditions represented. The name of the article was misleading since its labeling failed to reveal the fact, material in the light of such name, that the article was not, because of its sulfathiazole content, of value for disease conditions affecting the nose.

DISPOSITION: May 24 and June 23, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1641. Misbranding of Sinudrene. U. S. v. 5 Dozen Bottles and 3¾ Dozen Bottles of Sinudrene. Default decree of condemnation and destruction. (F. D. C. No. 15085. Sample Nos. 93228-F, 93229-F.)

LIBEL FILED: January 25, 1945, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about April 17 and November 28, 1944, by Davart Products, from Ashland, Ky.

PRODUCT: 5 dozen 1-ounce bottles and 3¾ dozen 2-ounce bottles of *Sinudrene* at Charleston, W. Va. Examination of samples disclosed that the product consisted essentially of ephedrine, water, glycerin, small amounts of phenol and iodides, and trace of malachite green.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements, "Sinudrene * * * for the relief of painful and congested sinus conditions. Promotes Drainage * * * In severe cases * * * allow Sinudrene to penetrate the sinuses more quickly. * * * Simple Hay Fever and Catarrh," were false and misleading since the product would not be effective in the treatment of painful and congested sinus conditions, hay fever, and catarrh, and would not be effective to promote drainage.

DISPOSITION: May 23, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1642. Misbranding of Kalergin Tablets. U. S. v. 30 Bottles of Kalergin Tablets. Default decree of condemnation and destruction. (F. D. C. No. 15852. Sample No. 29072-H.)

LIBEL FILED: April 2, 1945, Northern District of California.

ALLEGED SHIPMENT: On or about November 2, 1944, from Brooklyn, N. Y., by the United Cigar-Whelan Stores Corporation.

PRODUCT: 30 100-tablet bottles of *Kalergin Tablets* at San Francisco, Calif. Analysis showed that the product was a 5-grain potassium chloride tablet.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "For the temporary relief of allergic symptoms due to pollen sensitivity," was false and misleading since the article would not be effective in the relief of such symptoms.

DISPOSITION: May 16, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

1643. Misbranding of Apco Apcolene and Apco Brooder and Litter Spray. U. S. v. The American Products Co., Inc. Plea of guilty. Fine, \$300 and costs. (F. D. C. No. 14291. Sample Nos. 40527-F, 40529-F, 72380-F.)

INFORMATION FILED: April 7, 1945, District of Kansas, against the American Products Co., Inc., Kansas City, Kans.

ALLEGED SHIPMENT: On or about April 10 and May 18, 1944, from the State of Kansas into the State of Iowa.

PRODUCT: Analyses disclosed that a portion of the *Apco Apcolene* was a purple-red liquid with a red-brown sediment, containing, in aqueous solution, copper sulfate, iron sulfate, manganese sulfate, magnesium sulfate, and propylene glycol, colored with FD & C Red No. 2; that the remainder of the *Apco Apcolene* consisted chiefly of water and copper, iron, aluminum, magnesium, and manganese sulfates, colored with a red dye; and that the *Apco Brooder and Litter Spray* was a dark brown, oily liquid with a small amount of brown sediment and consisting chiefly of coal-tar hydrocarbons and phenolic compounds.

NATURE OF CHARGE: *Apco Apcolene*, misbranding, Section 502 (a), certain statements appearing upon accompanying placards and circulars entitled "Fight Coccidiosis," "Mycosis-Fungi," "Doc Apco Sez * * * Directions [including diagnosis and treatment charts]," "Auto Diagnosis Disease Chart," and "Apco A Drinking Water Medicine * * * Apcolene," were false and misleading since the article would not be efficacious for the purposes stated and implied. The statements represented and suggested that the article would be efficacious in increasing the health and vigor of poultry; that it would be efficacious in the cure, mitigation, treatment, and prevention of coccidiosis, blackhead, microscopic parasites, and mycosis; that it would save poultry flocks and keep poultry alive; that it would save the lives of sick and dying chickens, turkeys, and other poultry; and that it would result in continued and increased production of eggs.

Apco Brooder and Litter Spray, misbranding, Section 502 (a), certain statements upon an accompanying placard and circular entitled "Fight Coccidiosis" were false and misleading since the article would not be efficacious for the purposes stated and implied. The statements represented and suggested that the article, when used in compliance with specific directions for cleaning and disinfecting poultry brooder and laying houses, would be efficacious in the prevention and would aid in the treatment of coccidiosis.

DISPOSITION: April 24, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$100 on each of 3 counts, a total fine of \$300, plus costs.

1644. Misbranding of Hilltop Wor-Mor, K-M, and Mor-O. U. S. v. Fred H. Moore (Hilltop Laboratories and Hilltop Specialties Co.). Plea of nolo contendere. Fine, \$900. (F. D. C. No. 12534. Sample Nos. 8765-F to 8767-F, incl.)

INFORMATION FILED: September 26, 1944, District of Minnesota, against Fred H. Moore, trading as the Hilltop Laboratories and the Hilltop Specialties Co., Minneapolis, Minn.

ALLEGED SHIPMENT: On or about March 17 and May 14, 1943, from the State of Minnesota into the State of Wisconsin.

PRODUCT: Analyses disclosed that the *Wor-Mor* consisted essentially of copper sulfate, 27.87 percent, kamala, areca nuts, nux vomica (strychnine), phenothiazine, iron sulfate, anise, and nicotine sulfate (nicotine 0.31 percent); that the *K-M* consisted of a reddish colored solution containing, essentially, potassium chlorate, saltpeter (potassium nitrate), epsom salt (magnesium sulfate), potassium dichromate, and water; and that the *Mor-O* consisted of a powder containing, essentially, sodium hyposulfite, catechu, and a small amount of lactic acid, with an odor of anise.

LABEL, IN PART: "Hilltop * * * *Wor-Mor* Powder [or "*K-M* Intestinal Astringent for Poultry of All Ages," or "*Mor-O* Poultry Drinking Water Powder"]."

NATURE OF CHARGE: *Wor-Mor*, misbranding, Section 502 (a), certain statements on the label and in accompanying circulars entitled "Poultry Health News," and "For Victory Help Your Flock Guard Against Worm Sabotage," were false and misleading since they represented and suggested that the article contained 45 percent of copper sulfate; that it would be efficacious in the cure, mitigation, treatment, and prevention of worms, including large roundworms, in turkeys and chickens; that it would aid in maintaining poultry health; that it would keep hens worm-free; that it was effective in worm prevention and worm control; that it would be efficacious in the removal of roundworms and the desegmentation of large tapeworms; that the use of the article would prevent fowls from getting run-down from infestation with worms; and that it would aid the poultry raiser to make a profit. The article contained not more than 27.87 percent of copper sulfate, and it would not be efficacious for the purposes represented.

K-M, misbranding, Section 502 (a), certain statements on the labels and in the circulars entitled "Poultry Health News," and "For Victory Help Your Flock Guard Against Worm Sabotage," which were delivered by the defendant's salesman prior to the date of the shipment of the article, were false and misleading since they represented and suggested that the article would be an effective treatment for growing and laying stock that was not in a thrifty condition; that it would aid in stimulating the appetite and would aid all poultry; that it would be efficacious in the cure, mitigation, treatment, and prevention of mycosis and blackhead in turkeys, coccidiosis in turkeys and chickens, and diarrhea in old hens and baby chicks; that it would be efficacious to build resistance to disease in turkeys and chickens and to keep them in good health and regularly gaining weight; that it would be efficacious as an aid in starting poults and in keeping mature turkeys in prime condition; that it would help the digestion of the egg yolk and act as a bowel regulator in young poults; and that it would be efficacious as a tonic to run-down birds after outbreaks of coccidiosis, blackhead, and intestinal disorders. The labeling also bore statements representing and suggesting that the *K-M* would lessen the death loss in baby chicks and increase their growth; that it would be efficacious in preventing epidemics; that it possessed curative and tonic properties which would produce amazing results; that, when used in conjunction with *Mor-O*, it would be efficacious in the treatment of coccidiosis when it was violent and when droppings were bloody, caused by hemorrhages in the intestines; and that, when used in conjunction with *Wor-Mor Tablets*, it would help hens stay free from worms and would be an efficacious tonic after worming. The article did not possess curative and tonic properties which would produce amazing results, and it would not be efficacious for the purposes represented.

Mor-O, misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Poultry Health News" were false and misleading since they represented and suggested that the article would be an effective aid in the control of coccidiosis; and that, when used in conjunction with *K-M* (sometimes known as "*Kure-Mor*"), the article would be efficacious in the treatment of coccidiosis when it was violent and when droppings were bloody, caused by hemorrhages in the intestines. The article would not be efficacious for such purposes.

DISPOSITION: June 28, 1945. A plea of nolo contendere having been entered, the court imposed a fine of \$300 on each of the 3 counts.

1645. Misbranding of Necro Tonic For Swine. U. S. v. John R. MacDonald (Vitamized Feed Co.). Plea of *nolo contendere*. Fine, \$400 and costs. (F. D. C. No. 12557. Sample No. 8418-F.)

INFORMATION FILED: December 14, 1944, Northern District of Iowa, against John R. MacDonald, trading as the Vitamized Feed Co., Fort Dodge, Iowa.

ALLEGED SHIPMENT: On or about August 11, 1943, from the State of Iowa into the State of Minnesota.

PRODUCT: Analysis disclosed that the product contained essentially sodium thiosulfate, iron sulfate, copper sulfate, copper sulfide, sulfur, and potassium iodide, and water flavored with oil of anise.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "Necro Tonic For Swine," and certain statements in an accompanying circular entitled "Directions for Administering Doctor MacDonald's Swine Tonic," were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of necro in swine, whereas the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear a statement of each active ingredient by its common or usual name.

It was also alleged that certain other articles, *Dr. MacDonald's Vitamized Egg Mash Maker*, *Chick and Growing Mash Maker*, and *Vitamized Metabolators For Dairy Cattle, Sheep, Beef Cattle, Calves, and Swine*, were misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

DISPOSITION: June 12, 1945. A plea of *nolo contendere* was entered by the defendant, and the court imposed a fine of \$400 and costs.

1646. Misbranding of ChaRem. Chamberlain Dry Dip, and Chamberlain Worm Expeller. U. S. v. F. B. Chamberlain Co. Pleas of *nolo contendere* on counts 1 and 3; plea of guilty on count 2. Fine, \$625. (F. D. C. No. 14282. Sample Nos. 62531-F, 80401-F, 80402-F.)

INFORMATION FILED: February 19, 1945, Eastern District of Missouri, against the F. B. Chamberlain Co., a corporation, St. Louis, Mo.

ALLEGED SHIPMENT: On or about February 1 and 4, 1944, from the State of Missouri into the State of Illinois.

PRODUCT: Analyses disclosed that the *Worm Expeller* consisted chiefly of sodium sulfate, epsom salt, sodium bicarbonate, ferrous sulfate, ground areca nuts, and a small amount of whole American wormseed and kamala; that the *Dry Dip* consisted chiefly of kaolin, organic matter not identified, small proportions of sodium fluoride, and phenol compounds; and that the *ChaRem* consisted essentially of water, sugar, creosote, sodium hydroxide, a laxative plant drug, and a minute amount of arsenic.

NATURE OF CHARGE: *Worm Expeller*, misbranding, Section 502 (a), the label statement, "Worm Expeller for Hogs," was false and misleading since the article would not be efficacious to expel worms from hogs.

ChaRem, misbranding, Section 502 (a), certain statements in accompanying circulars entitled "How to Keep Your Chickens Healthy," and "Coccidiosis Kills Millions of Chickens Every Year," were false and misleading since the article would not be efficacious for the purposes stated and implied. The statements represented and suggested that the article would disinfect drinking water for use by chicks, chickens, and turkeys; that it would be efficacious in the treatment and prevention of blackhead in turkeys; that it would be efficacious in the prevention of coccidiosis (both bloody type and chronic), bronchitis, respiratory diseases, range paralysis, bowel trouble, and mycosis in chickens; and that it would be efficacious in the treatment of coccidiosis (bloody type), bronchitis (noninfectious type), limberneck, and general bowel disorder (not pullorum) in chickens.

Dry Dip, misbranding, Section 502 (a), the label statements which represented and suggested that the article, when used as directed, would be efficacious in the cure, mitigation, treatment, and prevention of colds, flu, and other diseases of the respiratory tract in hogs, were false and misleading since the article would not be efficacious for those purposes.

DISPOSITION: April 19, 1945. Pleas of *nolo contendere* on counts 1 and 3, relating to the *Worm Expeller* and *Dry Dip*, and a plea of guilty on count 2, relating to the *ChaRem*, having been entered on behalf of the defendant, the court

imposed a fine of \$25 on count 1, \$500 on count 2, and \$100 on count 3, a total fine of \$625.

1647. Misbranding of Sep-Tone. U. S. v. 10 Bottles, 4 Bottles, and 2 Jugs of Sep-Tone, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 15276. Sample Nos. 22110-H to 22112-H, incl.)

LIBEL FILED: February 16, 1945, Southern District of Illinois; amended libel subsequently filed.

ALLEGED SHIPMENT: By D. D. Dolan, from Dolan Laboratories, St. Louis, Mo. A portion of the drug was shipped on or about November 7, 1944, and the remainder, together with the printed matter, was shipped on or about January 6, 1945.

PRODUCT: 10 1-quart bottles, 4 ½-gallon bottles, and 2 1-gallon jugs of *Sep-Tone*, a placard headed "A High Grade Intestinal Antiseptic," and approximately 50 circulars entitled "Save your share of that 35% of U. S. Poultry Loss," at Edwardsville, Ill.

Examination disclosed that the drug consisted essentially of water, with small amounts of potassium dichromate; sodium, zinc, and copper sulfocarbates; ammonium chloride, and an iodide.

LABEL, IN PART: "Sep-Tone For Poultry Drinking Water," or "Sep-Tone A High Grade Astringent Intestinal Antiseptic."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following and similar statements in the labeling were false and misleading: (Label) "Sep-Tone A High Grade Astringent Intestinal Antiseptic For Medicating the Drinking Water * * * indicated in the treatment of enteritis, Cholera, Typhoid, Colds, coccidiosis, Bronchitis and other bacterial infections," and "Sep-Tone For Poultry Drinking Water"; (circulars) "Sep-Tone will do more towards helping relieve both digestive and respiratory troubles than any other two or three remedies combined. * * * Sep-Tone has apparently done wonders for us in cutting down mortality from colds, bronchitis, mycosis and digestive troubles and helping to keep our birds in tip-top condition"; and (placards) "A high-grade intestinal antiseptic and astringent for poultry drinking water."

DISPOSITION: May 4, 1945. No claimant having appeared, judgment of condemnation was entered and the drug, together with the printed matter, was ordered destroyed.

1648. Misbranding of Diarex, Swinade, Lax-A-Ton, Necor for Swine, and Pine-O-Mist. U. S. v. 20 Cartons of Diarex, 26 Cartons of Swinade, 4 Bottles and 32 Jugs of Lax-A-Ton, 3 Cartons and 1 Package of Necor for Swine, 42 Bottles of Pine-O-Mist, and a quantity of printed matter (and 2 other seizure actions against Diarex, Swinade, Lax-A-Ton, and Pine-O-Mist). Default decrees of condemnation and destruction. (F. D. C. Nos. 15348, 15351, 15355. Sample Nos. 87594-F to 87598-F, incl., 97717-F to 97723-F, incl.)

LIBELS FILED: March 15 and 17, 1945, District of Minnesota and District of South Dakota.

ALLEGED SHIPMENT: Between the approximate dates of October 15 and December 26, 1944, from Bensenville, Ill., by the Central Laboratories.

PRODUCT: 48 cartons of *Diarex*, 30 cartons and 36 cans of *Swinade*, 25 bottles and 32 jugs of *Lax-A-Ton*, 3 cartons and 1 package of *Necor for Swine*, 73 bottles of *Pine-O-Mist*, and quantities of accompanying leaflets at Redwood Falls, Minn., and Labolt and Artesian, S. Dak.

Examination of samples disclosed that the *Diarex* consisted essentially of bismuth subnitrate and subcarbonate, phenyl salicylate, tannic acid, sodium bicarbonate, and calcium and magnesium carbonates; that the *Swinade* consisted essentially of sulfur, iron sulfate, mandrake, strychnine-bearing material, corn meal, hydrated lime, and a magnesium compound; that the *Lax-A-Ton* was an aqueous solution containing, principally, potassium nitrate, potassium chlorate, potassium dichromate, and magnesium sulfate; that the *Necor for Swine* consisted of a gray powder containing, chiefly, magnesium and iron sulfates, small amounts of cobalt and manganese compounds, yeast, phosphate, sodium chloride, calcium carbonate, and nicotine; and that the *Pine-O-Mist* consisted essentially of creosote, guaiacol, camphor, oil of eucalyptus, pine oil, isopropyl alcohol, and water.

NATURE OF CHARGE: *Diarex*, misbranding, Section 502 (a), certain statements on its label and in an accompanying leaflet entitled "Scour Losses Reduced

in Livestock of All Ages by Using Diarex" were false and misleading since the statements and the name "Diarex" represented and suggested that the article would be effective in the treatment of scours and diarrhea in livestock and would prevent such conditions, whereas the article would not be effective in the treatment or prevention of such conditions.

Swinade, misbranding, Section 502 (a), certain statements on its label and in an accompanying leaflet entitled "Hog Sense" were false and misleading since they represented and suggested that the article would be effective in the removal of intestinal parasites, including large roundworms, from swine, whereas the article would not be effective for such purposes.

Lax-A-Ton, misbranding, Section 502 (a), certain statements on its label and in accompanying leaflets entitled "The Early Worm Gets The Bird," and "Protect Your Poultry Investment," were false and misleading since they represented and suggested that the article would be effective to combat such disease conditions of poultry as paralysis, coccidiosis, mycosis, worms, etc., to bring about "Internal sanitation," and to act as an intestinal astringent, whereas the article would not be effective for such purposes.

Necor for Swine, misbranding, Section 502 (a), the name of the article and certain statements on its label and in an accompanying leaflet entitled "What About Necro?" were false and misleading since the name and the statements represented and suggested that the article would be effective in the treatment and prevention of the serious diseases of swine known as necro, or necro enteritis, and of infectious enteritis, whereas the article would not be effective in the treatment and prevention of such diseases; and, Section 502 (i) (1), the carton containing the article was so filled as to be misleading, since the powder contained in the carton occupied only about 48 percent of the volume of the carton.

Pine-O-Mist, misbranding, Section 502 (a), certain statements on the label and in an accompanying leaflet entitled "Coughs and Sneezes Spread Diseases" were false and misleading since they represented and suggested that the article would be an effective remedy and preventive for roup, pneumonia, bronchitis, and fowl pox, and other respiratory diseases of fowls, and for respiratory diseases of swine, including influenza and colds, whereas the article would not be an effective remedy and preventive for those diseases and conditions.

DISPOSITION: April 30 and June 8, 1945. No claimant having appeared, judgments of condemnation were entered and the products, together with the leaflets, were ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS¹

1649. Misbranding of isopropyl alcohol compound. U. S. v. 587 Dozen Bottles of Isopropyl Alcohol Compound. Consent decree of forfeiture. Product ordered released under bond. (F. D. C. No. 15865. Sample Nos. 24339-H, 24343-H.)

LIBEL FILED: April 11, 1945, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about January 5 and July 23, 1943, by the Gold Medal Coffee Co., Inc., from Houston, Tex.

PRODUCT: 587 dozen bottles of *isopropyl alcohol compound* at New Orleans, La. Examination showed that all bottles contained less than 1 pint of the product and not more than 63.3 percent by volume of isopropyl alcohol.

LABEL, IN PART: "Krauss' Special One Pint Isopropyl Alcohol Compound 70%."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents since each bottle contained less than "One Pint"; and, Section 502 (e) (2), the label failed to state the quantity or proportion of isopropyl alcohol in the article, since the label statement "70%" was incorrect.

DISPOSITION: May 2, 1945. The Gold Medal Coffee Co., Inc., claimant, having admitted the allegations of the libel, judgment of forfeiture was entered and the product was ordered released under bond to be reprocessed under the supervision of the Food and Drug Administration.

¹ See also Nos. 1601, 1603, 1636, 1645.

1650. Misbranding of estrogenic substance powder. U. S. v. 6 Grams of Estrogenic Substance Powder. Decree of condemnation. Product ordered released under bond. (F. D. C. No. 15269. Sample No. 31201-H.)

LIBEL FILED: February 13, 1945, Southern District of California.

ALLEGED SHIPMENT: On or about November 27, 1944, by the Hema Drug Co., Inc., from Maspeth, N. Y.

PRODUCT: 6 grams of *estrogenic substance powder* at Los Angeles, Calif.

LABEL, IN PART: "Estrogenic Substance Powder."

NATURE OF CHARGE: Misbranding, Section 502 (e), the label of the article failed to bear the common or usual name of its active ingredients.

DISPOSITION: March 5, 1945. The Hema Drug Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

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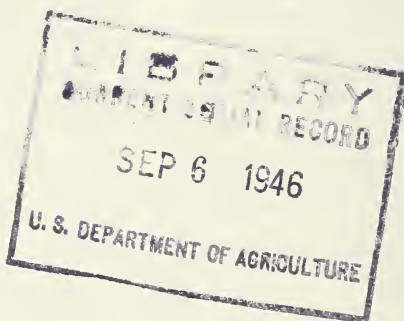
PRODUCTS

	N. J. No.		N. J. No.
Alcohol compound, isopropyl.....	1649	Lubricating jelly.....	1622
Apco Apcolene and Apco Brooder and Litter Spray.....	1643	Manna Arabian Tea.....	1634
Asthma, remedy for.....	1639	Munyon's Remedy for Round Worms and Munyon's Im- proved Paw-Paw Pills (Mun- yon's Laxative Pills).....	1601
Bandages and compresses....	1624-1627	Nasal jelly.....	1640
Burma Foot Cream.....	1633	Necor for Swine.....	1648
Calamus.....	1605	Necro Tonic for Swine.....	1645
Chamberlain Dry Dip and Cham- berlain Worm Expeller.....	1646	Northen's, Dr. Charles, Minerals and B Vitamins and Dr. Charles Northen's Minerals.....	1637
ChaRem.....	1646	Parenteral drugs.....	1609-1613
Cherry bark, wild.....	1619	Pepotabs Tablets.....	1602
Compresses. <i>See</i> Bandages and compresses.....		Pine-O-Mist.....	1648
Concentra.....	1635	Prentils.....	1603
Cotton, absorbent.....	1623	Prophylactics.....	1628-1632
Dandelion root.....	1621	Rejuvenators.....	1602, 1639
Devices.....	1628-1632	Rhubarb root, Indian.....	1604
Dextrose in physiological solution of sodium chloride.....	1610, 1612	SNJ Sulfathiazole Nasal Jelly.....	1640
Diarex.....	1648	Salt solutions, physiological.....	1610, 1612
Duchex.....	1614	Scammony root.....	1606
Estrogenic material, in oil.....	1613	Sep-Tone.....	1647
powder.....	1650	Sinudrene.....	1641
Foot cream.....	1633	Sodium citrate solution.....	1611
George's Rx 205 Tablets.....	1602	Special S. C. Red Tablets.....	1615
Germicide.....	1614	Stramonium leaves.....	1605
Ginger root.....	1618	Sulf Liquid Sulphur.....	1636
Glanzyme Nos. 1, 2, 3, and 6.....	1639	Swinade.....	1648
Hilltop Wor-Mor, K-M, and Mor-O.....	1644	Thiamine hydrochloride tablets.....	1617
Hi-Test Vegetable Compound with Thiamin Chloride.....	1616	Valerian root.....	1620
Injection preparations. <i>See</i> Par- enteral drugs.....		Veterinary preparations.....	1643-1648
Kalergin Tablets.....	1642	Vitamin preparations.....	1616, 1617, 1637
Laxative without required warn- ing statements.....	1601	B ₁ tablets.....	1617
Lax-A-Ton.....	1648	Vivogen.....	1638
Liver injection.....	1609	Water for injection.....	1611
		Women's disorders, remedies for.....	1639
		Wormseed, American.....	1607
		Wormwood.....	1608

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Akron Drug and Sundries Co.:		Hachmeister, Inc.:	
prophylactics-----	1632	Duchex-----	1614
Allied Pharmacal Co.:		Halperin, A. E., Co., Inc.:	
Hi-Test Vegetable Compound		adhesive compresses and adhe-	
with Thiamin Chloride-----	1616	sive bandages-----	1624
American Products Co., Inc.:		Hampton Manufacturing Co.:	
Apco Apcolene and Apco		adhesive strips-----	1626
Brooder and Litter Spray-----	1643	Hauptman, G. F.:	
American White Cross Labora-		George's Rx 205 Tablets and	
tories, Inc.:		Pepotabs Tablets-----	1602
absorbent cotton-----	1623	Hema Drug Co., Inc.:	
Aronab Products Co.:		estrogenic substance powder--	1650
prophylactics-----	1628	Hilltop Laboratories, <i>See</i> Moore,	
Associated Ross-Good Labora-		F. H.	
tories:		Hilltop Specialties Co. <i>See</i>	
estrogenic material in oil-----	1613	Moore, F. H.	
Baer, Samuel, Sr., & Sons:		Ivers-Lee Co.:	
American wormseed-----	1607	Prentils-----	1603
Belmont Co. <i>See</i> Sexton Drug		Jay Dee Drug Co.:	
Store.		prophylactics-----	1632
Central Laboratories:		Kachurin Drug Co.:	
Diarex, Swinade, Lax-A-Ton,		valerian root-----	1620
Necor for Swine, and Pine-		Killian Manufacturing Co.:	
O-Mist-----	1648	prophylactics-----	1632
Chamberlain, F. B., Co.:		Lee, C. L., & Co., Inc.:	
ChaRem, Chamberlain Dry Dip,		adhesive strips-----	1627
and Chamberlain Worm Ex-		MacDonald, J. R.:	
peller-----	1646	Necro Tonic for Swine-----	1645
Colloidal Products:		McNeil Laboratories:	
Dr. Charles Northen's Minerals		lubricating jelly-----	1622
and B Vitamins and Dr.		Market Drug Co. <i>See</i> Haupt-	
Charles Northen's Minerals--	1637	man, G. F.	
Cutter Laboratories:		Moore, F. H.:	
dextrose in isotonic solution of		Hilltop Wor-Mor, K-M, and	
sodium chloride-----	1612	Mor-O-----	1644
Davart Products:		Munyon Remedy Corp.:	
Sinudrene-----	1641	Munyon's Remedy for Round	
Dean Rubber Manufacturing Co.:		Worms and Munyon's Im-	
prophylactics-----	1631	proved Paw-Paw Pills (Mun-	
Dietz, Charles H., Inc.:		yon's Laxative Pills)-----	1601
Special S. C. Red Tablets-----	1615	Newman, Hardy, & Co.:	
thiamine hydrochloride tablets--	1617	prophylactics-----	1629
Dolan, D. D.:		Nichols, C. W.:	
Sep-Tone-----	1647	Manna Arabian Tea-----	1634
Dolan Laboratories. <i>See</i> Dolan,		Penn Drug & Supply Co.:	
D. D.		Munyon's Remedy for Round	
Drug Products Co.:		Worms and Munyon's Im-	
liver solution-----	1609	proved Paw-Paw Pills (Mun-	
Ewing, S. H., Ltd.:		yon's Laxative Pills)-----	1601
ginger root-----	1618	Readyflask, Inc.:	
Ferrell, Jean, Inc.:		isotonic solution of three chlo-	
Concentra-----	1635	rides and dextrose in isotonic	
Flores, Rodolfo L. y Cia.:		solution of sodium chloride--	1610
wormwood-----	1608	Reed, W. H., & Co.:	
General Bandages, Inc.:		prophylactics-----	1630
Gauztex-----	1625	Ryer Dietary Supplements Co.:	
Gold Medal Coffee Co., Inc.:		Glanzymes-----	1639
isopropyl alcohol compound---	1649	S. N. J. Products Co.:	
Greer Drug Co.:		SNJ Sulfathiazole Nasal Jerry--	1640
wild cherry bark-----	1619	St. Louis Commission Co.:	
Gutierrez, Belarmino:		stramonium leaves and cala-	
scammony root-----	1606	mus-----	1605

	N. J. No.		N. J. No.
Sanette Mfg. Co.:		Uniplast Surgical Dressing Co.:	
adhesive strips-----	1627	adhesive bandages-----	1624
Sexton Drug Store:		United Cigar - Whelan Stores	
Burma Foot Cream-----	1633	Corp.:	
Sharp and Dohme, Inc.:		Kalergin Tablets-----	1642
water for injection and solu-		Vitamized Feed Co. See Mac-	
tion of sodium citrate-----	1611	Donald, J. R.	
Smith Crude Drug & Spice Co.:		Vivogen Co.:	
Indian rhubarb root-----	1604	Vivogen-----	1638
Sulco Products Corp.:		Whelan Stores. See United Ci-	
Sulf Liquid Sulphur-----	1636	gar-Whelan Stores Corp.	



FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1651-1700

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., August 14, 1946.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1651. Misbranding of Diettes. U. S. v. 36 Boxes of Diettes. Default decree of condemnation and destruction. (F. D. C. No. 16381. Sample No. 22479-H.)

LIBEL FILED: June 26, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about January 13, 1945, by the Health Sales Co., from St. Louis, Mo.

PRODUCT: 36 boxes, each containing 60 lozenges, of *Diettes*, at Lincoln, Ill. Analysis showed that the product consisted essentially of thyroid, $\frac{1}{4}$ grain per tablet, phenolphthalein, $\frac{1}{4}$ grain per tablet, chocolate, and sugar.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in an accompanying circular entitled, "Diettes and the Treatment of Obese Conditions," which represented and suggested that the article would be a safe and effective treatment for obesity, were false and misleading since it would not be a safe or effective treatment for obesity.

Further misbranding, Section 502 (e), the label of the article failed to bear the common or usual name of each active ingredient since it did not reveal the presence of phenolphthalein; and, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency prescribed in the labeling, namely, "One lozenge dissolved on the tongue or chewed like

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1651, 1653, 1656, 1674, 1686, 1696, 1697; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1656; inconspicuousness of required label information, No. 1666; failure to comply with the packaging requirements of an official compendium, Nos. 1666-1668; cosmetics, subject to the drug provisions of the Act, Nos. 1654, 1685, 1686.

candy one hour before each meal and at bedtime. This dosage may be increased by taking an extra one at luncheon and dinner."

DISPOSITION: July 28, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1652. Misbranding of vitamin D capsules. U. S. v. 7 Bottles of Vitamin D capsules and a number of folders and leaflets. Default decree of condemnation and destruction. (F. D. C. No. 16068. Sample No. 4125-H.)

LABEL FILED: April 27, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: By the Battle Creek Dietetic Supply Co., from Battle Creek, Mich. The product was shipped on or about February 12 and 22, 1945, and the folders and leaflets were shipped on various unknown dates.

PRODUCT: 5 50-capsule bottles and 2 100-capsule bottles of *vitamin D capsules*, 500 folders entitled "Superb Health," and 75 leaflets entitled "Hidden Hunger" at Philadelphia, Pa. Examination showed that the capsules contained vitamin D in oil.

LABEL, IN PART: "Health House Brand Vitamin D Each capsule contains not less than 50,000 U. S. P. Units of Vitamin D."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the folders and leaflets were false and misleading since they represented and suggested that the article would be safe and effective in the treatment of arthritis, whereas the article would not be safe and effective in the treatment of arthritis; and, Section 502 (j), the article would be dangerous to health when taken in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, "one capsule four times daily the first month increasing one capsule daily per week up to ten capsules daily."

DISPOSITION: May 22, 1945. No claimant having appeared, judgment of condemnation was entered and the product, together with the printed matter, was ordered destroyed.

1653. Misbranding of DPS Formula 75 Vitamin Capsules. U. S. v. 18 Bottles of DPS Formula 75 Vitamin Capsules. Default decree of condemnation and destruction. (F. D. C. No. 15481. Sample No. 26542-H.)

LABEL FILED: On or about March 12, 1945, District of Colorado.

ALLEGED SHIPMENT: On or about January 22 and February 12, 1945, by the Dartell Laboratories, from Los Angeles, Calif.

PRODUCT: 18 bottles of *DPS Formula 75 Vitamin Capsules* at Denver, Colo.

LABEL, IN PART: (Bottle) "100 * * * Perles Formula 75 Each perle contains irradiated ergosterol in wheat germ oil, enclosed in a gelatin perle providing: 50,000 U. S. P. Units Vitamin D."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "four perles daily * * * Four perles will provide 200,000 U. S. P. Units vitamin D."

DISPOSITION: May 14, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1654. Misbranding of vitamin and drug products. U. S. v. 18 Packages of Vitamin C Tablets, 8 Packages of Natural Vitamin B₂ (G) Tablets, 13 Packages of Wheat Germ Oil Capsules, 15 Packages of Natural Fruit Laxative, 5 Packages of Mode Paree Scalp Ointment, 22 Packages of Mode Paree Aene Cream, 21 Packages of American's Hair Growing Aid, 10 Packages of Miracle Cream, 26 Packages of Miracle Aid, and a number of catalogs. Default decree of condemnation and destruction. (F. D. C. No. 16073. Sample Nos. 20344-H to 20347-H, incl., 20350-H to 20355-H, incl.)

LABEL FILED: On or about May 9, 1945, Western District of Missouri.

ALLEGED SHIPMENT: By the American Beauty Products Co., from Chicago, Ill. The products were shipped between the approximate dates of October 30, 1943, and April 18, 1945, and the catalogs were shipped on or about February 10, 1945.

PRODUCT: Vitamin and drug products as set forth above, and a number of accompanying catalogs entitled "City Catalog No. 81" at Kansas City, Mo.

Examination showed that the *vitamin C tablets* contained ascorbic acid; that the *vitamin B₂ tablets* contained vitamin B₂; that the *wheat germ oil capsules* contained an oil such as wheat germ oil; that the *Fruit Laxative* contained laxative plant drugs, including an emodin-bearing drug; that the *scalp ointment* contained sulfur in an ointment base; that the *acne cream* contained oil of cade in an ointment base; that the *hair growing aid* contained oil of cade or creosote in an ointment base; that the *Miracle Cream* contained epsom salt, sodium sulfate, a stearate, water, and a small proportion of methyl salicylate; and that the *Miracle Aid* consisted of water and a small proportion of albumin.

NATURE OF CHARGE: *Vitamin C tablets*, *vitamin B₂ (G) tablets*, and *wheat germ oil*, misbranding, Section 502 (a), the following statements in the catalog were false and misleading since the products would not be of value in the conditions stated and implied: "Vitamin C For Arthritic and Rheumatic Conditions * * * maintains normal health * * * for rheumatic fever and other fever conditions, wound healing, arthritis, anemia, infections, tuberculosis and peptic ulcer; * * * to help prevent tooth decay"; "Vitamin G (B₂) * * * Helps prevent stunting of growth in children, premature skin aging in adults and loss of hair. 10,000 micrograms daily relieves dim vision. Also contains calcium pantothenate (ANTI-GRAY HAIR FACTOR)"; "Wheat Germ Oil * * * Helps prevent miscarriage, acne, and certain skin conditions. Relieves hay fever, allergic asthma and muscular exhaustion."

Natural Fruit Laxative, misbranding, Section 502 (a), the name of the product, "Natural Fruit Laxative," was false and misleading since its laxative ingredients were not fruits, and the statement in the catalog, "Made from six tropical fruits * * Purifies the blood," was false and misleading as applied to a product of the composition and action of this laxative. Further misbranding, Section 502 (f) (2), its labeling failed to warn that frequent or continued use of the article might result in dependence upon laxatives.

Mode Parée Scalp Ointment, misbranding, Section 502 (a), the following statements on the package and in the catalog were false and misleading since the product would not be effective in preventing loss of hair or in the treatment of eczema and disorders of the scalp or skin: (Catalog) "For Many Scalp Ailments! Relieves * * * Eczema * * * Falling Hair, Skin and other scalp ailments"; (package label) "A treatment specially formulated for loss of hair * * * eczema and other scalp disorders. * * * in treatment of scalp disorders."

Mode Parée Acne Cream, misbranding, Section 502 (a), the following statements on the package and in the catalog were false and misleading since the product would not be effective in the treatment of acne: (Catalog) "Acne Cream * * * for treating mild cases of Acne"; (package label) "Acne Cream * * * for the treatment of mild cases of Acne * * * well-regulated Acne treatment. For more severe cases of Acne"; and, Section 502 (e) (2), the label failed to bear the common or usual name of each of the active ingredients of the article.

American's Hair Growing Aid, misbranding, Section 502 (a), the following statements on the package and in the catalog were false and misleading since the product would not be effective in promoting the growth of hair or in the treatment of tetter or conditions which retard the growth of hair: (Catalog) "Hair Growing Aid Excellent for treatment of dandruff, tetter and similar scalp irritations which retard the growth of healthy, normal hair"; (package label) "Hair Growing Aid * * * Tetter, etc."; and, Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient of the article.

Miracle Cream, misbranding, Section 502 (a), the following statements on the package and in the catalog were false and misleading since the product would not bring about a reduction in weight: (Catalog) "Hips, Hips Away—or Any Other Part of the Anatomy * * * Miracle Slenderizing Cream * * * for Spot Reducing Recommended by Reputable Physicians * * * Testimonial letters prove that some women have lost as much as 4½ inches in their abdomen in 3 weeks . . . 3 inches in hips in 2 weeks. One inch in thighs in one week! One inch in a double chin in one week"; (package label) "An Aid for Reducing."

Miracle Aid, misbranding, Section 502 (a), the following statements on the package and in the catalog were false and misleading since the product would not remove wrinkles and double chin: (Catalog) "Wrinkles and Double Chin Vanish with Miracle Aid Lotion * * * you feel a gentle tightening effect on the expression wrinkles and chin line. It is very effective if left on over night"; (package label) "For Wrinkles and Double Chin * * * Apply by patting with finger tips, on wrinkles and double chin."

DISPOSITION: June 26, 1945. No claimant having appeared, judgment of condemnation was entered and the products and catalogs were ordered destroyed.

1655. Misbranding of Dismuke's Pronto-Lax, Dismuke's Famous Mineral Crystals, Famous Residium, Dismuke's Nose Spraying Solution, and Dismuke's Eye Bath. U. S. v. 40 Bottles of Dismuke's Pronto-Lax, etc. Default decree of condemnation and destruction. (F. D. C. No. 16348. Sample Nos. 21861-H to 21865-H, incl.)

LIBEL FILED: June 23, 1945, Western District of Tennessee.

ALLEGED SHIPMENT: By the Famous Mineral Water Co., from Mineral Wells, Tex. The articles of drug were shipped on or about January 14 and April 3, 1945, and the circulars were shipped in December 1944.

PRODUCT: 40 bottles of *Dismuke's Pronto-Lax*, 6 boxes of *Dismuke's Famous Mineral Crystals*, 3 bottles of *Famous Residium*, 4 bottles of *Dismuke's Nose Spraying Solution*, 6 bottles of *Dismuke's Eye Bath*, and 500 white circulars entitled "Dismuke's Famous Mineral Water at the sign of the Old Mill" and 10 yellow circulars entitled "The Original and Genuine Famous Mineral Crystals," at Memphis, Tenn.

Examination showed that the *Pronto-Lax* consisted essentially of water and sodium sulfate, with small proportions of salt, sodium carbonate, sodium bicarbonate, and magnesium chloride; that the *mineral crystals* consisted essentially of sodium sulfate with small proportions of salt and sodium carbonate; that the *Residium* consisted essentially of water, salt, sodium sulfate, sodium carbonate, and sodium nitrite; that the *nose spraying solution* consisted essentially of water, salt, sodium sulfate, sodium carbonate, and sodium nitrite; and that the *eye bath* consisted essentially of water, salt, sodium sulfate, and sodium carbonate.

NATURE OF CHARGE: *Pronto-Lax*, misbranding, Section 502 (a), certain statements in the white circulars were false and misleading in that they represented and suggested that the article had been endorsed by the Food and Drug Administration; that it was a non-habit-forming laxative; that it was effective as a tonic; that it was effective to eliminate acid, waste, and toxic poisons from the system; and that it was effective in the treatment of diabetes, enlarged liver, carbuncles, stomach trouble, mucous colitis, sciatic rheumatism, constipation, stomach ulcers, and auto-intoxication. The article had not been endorsed by the Food and Drug Administration; it was a habit-forming laxative; and it was not effective for the symptoms, conditions, and diseases stated and implied. Further misbranding, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to warn that frequent and continued use might result in dependence upon laxatives.

Mineral crystals, misbranding, Section 502 (a), certain statements in the yellow circulars were false and misleading since they represented and suggested that the article would purify the system by flushing the intestinal tract; that it would often be beneficial after excessive eating or drinking; and that it would prove beneficial in treating acid stomach, colds, headaches, biliousness, indigestion, constipation, bad complexion, rheumatism, arthritis, neuritis, high blood pressure, and diabetes. The article would not be effective in the treatment of the conditions stated and implied. Further misbranding, Section 502 (a), the label statement, "Contents: Sodium Sulphate, Sodium Chloride, Magnesium Sulphate, Magnesium Carbonate, Calcium Carbonate, Iron and Aluminium Oxides," was misleading since it failed to reveal the material fact that sodium sulfate was the only active ingredient; and, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to warn that frequent and continued use might result in dependence upon laxatives.

Residium, misbranding, Section 502 (a), certain statements on the bottle label and in the white circulars were false and misleading since they represented and suggested that the article would be effective in the treatment of cuts, sores, burns, eczema, rash, poison ivy, indigestion, gastric ailments, acid

stomach, colic, and ulcerated stomach. The article would not be effective in the treatment of the conditions stated and implied.

Nose spraying solution, misbranding, Section 502 (a), certain statements on the bottle label and in the white circulars were false and misleading since they represented and suggested that the article would be effective in the treatment of head colds, hay fever, and sinus and catarrhal ailments. The article would not be effective for those purposes.

Eye bath, misbranding, Section 502 (a), certain statements in the white circulars which represented and suggested that the article would be beneficial in the treatment of eye strain, blue, granulated lids, and sore eyes were false and misleading since the article would not be effective in the treatment of the conditions stated and implied.

DISPOSITION: July 27, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1656. Misbranding of an unlabeled drug. U. S. v. 4 Unlabeled Tubes of a Certain Drug. Default decree of forfeiture and destruction. (F. D. C. No. 16148. Sample No. 17228-H.)

LABEL FILED: May 17, 1945, Southern District of Indiana.

ALLEGED SHIPMENT: On or about April 6, 1945, by the Don Curtis Keefer Laboratory, from Chicago, Ill.

PRODUCT: 4 unlabeled tubes of a certain drug at Brazil, Ind.

Analysis disclosed that the article consisted essentially of potassium soap, approximately 11.6 percent; sodium soap, approximately 11.0 percent; potassium iodide, approximately 5.7 percent; and water.

NATURE OF CHARGE: Misbranding, Section 502(b), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), it did not bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (1), it did not bear a label containing adequate directions for use.

DISPOSITION: June 30, 1945. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1657. Adulteration of posterior pituitary obstetrical and Ribothiaccine. U. S. v. Western Pharmacal Co. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 15562. Sample Nos. 15666-F, 74279-F.)

INFORMATION FILED: July 18, 1945, Southern District of California, against the Western Pharmacal Co., Los Angeles, Calif.

ALLEGED SHIPMENT: On or about July 6 and August 4, 1944, from the State of California into the States of Arizona and Texas.

LABEL, IN PART: "Soltan Posterior Pituitary Obstetrical U. S. P. XI * * * Manufactured for Soltan Corporation Los Angeles Calif."; and "Western Ribothiaccine A sterile solution."

NATURE OF CHARGE: *Posterior pituitary obstetrical*, adulteration, Section 501 (b), the article purported to be and was represented as a drug the names of which, "Solution of Posterior Pituitary U. S. P. XI" and "Posterior Pituitary Injection," are recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from, and its quality and purity fell below, the official standard since it possessed a physiological activity of not more than 22 percent of that required by the Pharmacopoeia; it contained undissolved material, which is not permitted in the official product; and its difference from the official standard was not plainly stated, or stated at all, on the label.

Ribothiaccine, adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was a solution of a soluble medicament intended for injection through the skin, and therefore should have been free from undissolved material, whereas the article was contaminated with undissolved material.

DISPOSITION: August 27, 1945. A plea of nolo contendere having been entered on behalf of the defendant, a fine of \$250 was imposed on each of the 2 counts.

1658. Adulteration and misbranding of Estrovin in Oil. U. S. v. 311 Boxes of Estrovin in Oil. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 15792. Sample No. 6202-H.)

LABEL FILED: On or about April 13, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about December 7, 1944, by the Adson-Intrasol Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: 311 boxes, each containing 25 ampuls, of *Estrovin in Oil*, at Newark, N. J. Examination showed that the product contained estradiol with a very small proportion of estrone.

LABEL, IN PART: (Box) "Estrovin (Estrogenic Hormones Substance) In Oil * * * 1 cc. contains 10,000 I. U. of Estrogenic Hormones Substance, obtained from Equine Urine."

NATURE OF CHARGE: Adulteration, Section 501 (d), an oil solution of estrogenic material consisting essentially of estradiol had been substituted in whole or in part for an oil solution of the estrogenic hormones substance obtained from equine urine.

Misbranding, Section 502 (a), the label statement, "1 cc. contains 10,000 I. U. of Estrogenic Hormones Substance, obtained from Equine Urine," was misleading since the estrogenic hormones substance contained in the article did not consist of estrogenic hormones naturally occurring in equine urine.

DISPOSITION: July 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution, after destruction of the labels under the supervision of the Food and Drug Administration.

1659. Adulteration of Estrinol. U. S. v. 96 Vials of Estrinol. Decree of condemnation. Product ordered released upon payment of costs. (F. D. C. No. 15880. Sample No. 4447-H.)

LABEL FILED: April 6, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 16, 1945, by the Bellevue Laboratories, Inc., from New York, N. Y.

PRODUCT: 96 30-cc. vials of Estrinol at Philadelphia, Pa. Examination showed that the estrogenic material present consisted essentially of estradiol with no significant proportion of estrone.

LABEL, IN PART: "30 cc. + Estrinol a purified preparation in sesame oil. Each c. c. is equivalent to 10000 I. U. of natural occurring estrogenic substances from pregnant mare urine containing principally estrone. Chlorbutanol 0.5% (Chloroform derivative)."

NATURE OF CHARGE: Adulteration, Section 501 (d), a preparation containing estrogenic material including little or no estrone had been substituted in whole or in part for a preparation of natural occurring estrogenic substances from pregnant mare urine containing, principally, estrone.

DISPOSITION: July 11, 1945. Bellevue Laboratories, Inc., having appeared as claimant, judgment of condemnation was entered and the product was ordered released, upon the payment of costs, to be relabeled under the supervision of the Food and Drug Administration.

1660. Adulteration of Hyposols Liver Solution. U. S. v. 20 Vials of Hyposols Liver Solution. Default decree of forfeiture and destruction. (F. D. C. No. 15900. Sample No. 11228-H.)

LABEL FILED: April 12, 1945, District of Vermont.

ALLEGED SHIPMENT: On or about January 15, 1945, by the Drug Products Co., from Long Island City, N. Y.

PRODUCT: 20 vials of *Hyposols Liver Solution* at Windsor, Vt. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "10 cc. Size Multiple Dose Vial Hyposols Liver Solution U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be liver injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

DISPOSITION: July 18, 1945. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1661. Adulteration of sodium salicylate. U. S. v. 475 Ampuls of Sodium Salicylate. Default decree of condemnation and destruction. (F. D. C. No. 16249. Sample No. 31527-H.)

LABEL FILED: May 26, 1945, Southern District of California.

ALLEGED SHIPMENT: On or about June 7, 1944, by the Cheplin Biological Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 475 ampuls of *sodium salicylate* at Los Angeles, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Salicylate," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: June 27, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1662. Adulteration of water for injection. U. S. v. 129 Vials of Water for Injection. Default decree of condemnation and destruction. (F. D. C. No. 16169. Sample No. 13845-H.)

LABEL FILED: May 10, 1945, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 14, 1945, by the Cheplin Biological Laboratories, Inc., Syracuse, N. Y.

PRODUCT: 129 vials of *water for injection* at Cleveland, Ohio.

LABEL, IN PART: "100 cc. Size Vial Water for Injection, U. S. P. (Sterile)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: June 8, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1663. Adulteration of isopropyl alcohol compound. U. S. v. 35% Dozen Bottles of Isopropyl Alcohol Compound. Default decree of condemnation and destruction. (F. D. C. No. 16267. Sample No. 10061-H.)

LABEL FILED: On or about June 8, 1945, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 3, 1945, by the Pennex Products Co., Inc., Pittsburgh, Pa.

PRODUCT: 35% dozen bottles of *isopropyl alcohol compound* at Youngstown, Ohio. Analysis showed that the article contained not more than 60 percent by volume of isopropyl alcohol.

LABEL, IN PART: "Hospital Isopropyl Alcohol Compound Isopropyl Alcohol 70% by volume * * * Contents One Pint."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

DISPOSITION: June 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1664. Adulteration and misbranding of Soltan Calcium Water. U. S. v. 278 Bottles of Soltan Calcium Water and a Number of Booklets. Default decree of destruction. (F. D. C. No. 16077. Sample No. 28380-H.)

LABEL FILED: May 4, 1945, Western District of Washington.

ALLEGED SHIPMENT: On or about March 15, 1945, by the Western Pharmacal Co., from Los Angeles, Calif.

PRODUCT: 278 1-quart bottles of *Soltan Calcium Water* and a stock of booklets entitled "Calcium" at Tacoma, Wash.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since each fluid ounce did not contain 10.17 grains of calcium, as stated on the labeling.

Misbranding, Section 502 (a), certain statements in the labeling were false and misleading.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7917, in which are set forth the results of analysis and the false and misleading statements referred to above.

DISPOSITION: June 16, 1945. No claimant having appeared, judgment was entered ordering that the product and the booklets be destroyed.

1665. Adulteration of phenothiazine drench. U. S. v. 30 Jugs of Phenothiazine Drench. Default decree of condemnation and destruction. (F. D. C. No. 16205. Sample No. 33145-H.)

LABEL FILED: On or about June 15, 1945, District of Kansas.

ALLEGED SHIPMENT: On or about February 2, 1945, by the Southwestern Salt and Supply Co., San Angelo, Tex.

PRODUCT: 30 1-gallon jugs of *phenothiazine drench* at Alma, Kans.

LABEL, IN PART: "Phenothiazine Drench For Sheep and Goats. Each Ounce Contains 12½ Gms."

NATURE OF CHARGE: Adulteration, Section 501 (c), analysis showed that the article contained not more than 10.35 grams of phenothiazine per fluid ounce, whereas it was represented to possess 12½ grams.

DISPOSITION: August 25, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1666. Adulteration and misbranding of adhesive strips. U. S. v. 32 Cartons of Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 16300. Sample No. 6815-H.)

LABEL FILED: June 1, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about December 11 and 14, 1944, by Gero Products, Inc., South Boston, Mass.

PRODUCT: 32 cartons, each containing 8 gross packages, of *adhesive strips* at New York, N. Y. Examination showed that the product was not sterile but was contaminated with living micro-organisms, and that it was not packaged in such manner that sterility would be maintained.

LABEL, IN PART: (Package) "Home-aid Brand 8 Adhesive Strips For Home, Factory and Sport Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (c), the name and place of business of the manufacturer, packer, or distributor, which the law requires to appear on the label, were not prominently placed thereon with such conspicuousness as to render them likely to be read by the ordinary individual under customary conditions of purchase and use, since they were illegible; and, Section 502 (g), the article was not packaged as prescribed in the United States Pharmacopoeia, which provides as follows: "Each Adhesive Absorbent Gauze is packaged individually in such manner that sterility is maintained until the individual package is opened. One or more individual packages are packed in a second protective container."

DISPOSITION: June 20, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1667. Adulteration and misbranding of adhesive strips. U. S. v. 11½ Gross Packages of Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 16315. Sample No. 6816-H.)

LABEL FILED: On or about June 4, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about February 14, 1945, by the Home-Aid Sales Co., South Boston, Mass.

PRODUCT: 11½ gross packages of *adhesive strips* at New York, N. Y. Examination showed that the product was not sterile but was contaminated with living micro-organisms, and that it was not packaged in such manner that sterility would be maintained.

LABEL, IN PART: "Home-aid Brand 8 Adhesive Strips For Home, Factory and Sport Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (g), the article was not packaged as prescribed in the United States Pharmacopoeia, which provides as follows: "Each Adhesive Absorbent Gauze is packaged individually in such manner that sterility is maintained until the individual package is opened. One or more individual packages are packed in a second protective container."

DISPOSITION: June 28, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1668. Adulteration and misbranding of adhesive gauze bandages. U. S. v. 5¼ Gross and 14¾ Gross Packages of Adhesive Gauze Bandages. Default decrees of condemnation and destruction. (F. D. C. Nos. 16311, 16313. Sample Nos. 18027-H, 31422-H.)

LIBELS FILED: On or about June 1 and 11, 1945, Northern District of Illinois and Southern District of California.

ALLEGED SHIPMENT: On or about February 17 and March 2, 1945, by the Gotham Sales Co., from New York, N. Y.

PRODUCT: 5¼ gross packages of *adhesive gauze bandages* at Chicago, Ill., and 14¾ gross packages of the same product at Los Angeles, Calif.

LABEL, IN PART: "Home-aid Brand 8 Adhesive Strips."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be a drug, "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (g), the article was not packaged as is prescribed in the United States Pharmacopoeia, which provides as follows: "Each Adhesive Absorbent Gauze is packaged individually in such manner that sterility is maintained until the individual package is opened. One or more individual packages are packed in a second protective container."

DISPOSITION: July 17 and September 26, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1669. Adulteration and misbranding of bandages. U. S. v. 31 Cases of Bandages. Consent decree of condemnation and destruction. (F. D. C. No. 16369. Sample No. 2759-H.)

LIBEL FILED: June 12, 1945, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about March 24, 1945, by Nu-Hesive, Inc., from Leominster, Mass.

PRODUCT: 31 cases, each containing 48 boxes, of bandages at Richmond (Bell-bluff), Va. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: (Boxes) "Bandage, Elastic All Cotton Self-Adherent 1 Dozen 2 inch; By 5 Yards. Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Sterilized" and "Sterile" were false and misleading.

DISPOSITION: On August 20, 1945, Nu-Hesive Inc., claimant, having requested the release of 5 boxes of the product for purposes of analysis, an order was entered granting that request. On December 10, 1945, the claimant having indicated that it did not desire to defend the matter further, and having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1670. Adulteration and misbranding of gauze pads. U. S. v. 46 Packages of Gauze Pads. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 16338. Sample No. 4610-H.)

LIBEL FILED: June 2, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 11, 1944, from Worcester, Mass., by the Handy Pad Supply Co.

PRODUCT: 46 packages of gauze pads at Philadelphia, Pa.

LABEL, IN PART: (Package) "100 Ideal Dispenser Type Gauze Pads Sterilized After Packaging."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Sterile Absorbent Gauze [Sterile Gauze]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statement, "Sterilized After Packaging," was false and misleading as applied to the article, which was not sterile but was contaminated with living micro-organisms.

DISPOSITION: August 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1671. Misbranding of estrogenic hormone. U. S. v. 87 Vials of Estrogenic Hormone. Default decree of condemnation. Product ordered delivered to a charitable organization. (F. D. C. No. 16241. Sample No. 22578-H.)

LIBEL FILED: May 25, 1945, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 27 and 28, 1945, from Philadelphia, Pa., by the National Drug Co.

PRODUCT: 87 vials of *estrogenic hormone* at St. Louis, Mo. Examination showed that the article was an oil solution containing estrogenic substances consisting essentially of estradiol with an insignificant amount, if any, of estrone which is the principal estrogenic hormone occurring in natural sources such as pregnant mares' urine.

LABEL, IN PART: "10 cc. Estrogenic Hormone 10,000 Injectosol * * * An estrus producing extract derived from pregnant mares' urine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "derived from pregnant mares' urine," was false and misleading since the estrogenic material present in the article did not consist of estrogenic substance as derived from the urine of pregnant mares.

DISPOSITION: July 10, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable organization on condition that the product be relabeled, under the supervision of the Federal Security Agency, to show that it was essentially estradiol.

1672. Misbranding of estrogenic substance in oil. U. S. v. 2,167 Vials of Estrogenic Substance in Oil. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16000. Sample Nos. 13251-H, 13252-H.)

LIBEL FILED: May 4, 1945, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 30 and March 5, 1945, by the Loeser Laboratory, Inc., from New York, N. Y.

PRODUCT: 2,167 20-cc. vials of *estrogenic substance in oil* at Cincinnati, Ohio. Examination showed that the product was an oil solution containing estrogenic substances consisting almost entirely of estradiol with an insignificant amount, if any, of estrone, which is the principal estrogenic hormone occurring in natural sources such as pregnant mares' urine.

LABEL, IN PART: "Proliculin Natural Estrogenic Substances in Oil [or "Proliculin Brand of Natural Estrogenic Substance in Oil"] * * * Derived from the urine of pregnant mares."

*See also Nos. 1651, 1652, 1654, 1655, 1658, 1664, 1669, 1670.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements, "Natural Estrogenic Substance [or "Substances"] in Oil" and "Natural Estrogenic Substance [or "Substances"] * * * Derived from the urine of pregnant mares," were false and misleading since the estrogenic material present did not consist of natural estrogenic substance as derived from the urine of pregnant mares.

DISPOSITION: June 18, 1945. The Wm. S. Merrell Co., Cincinnati, Ohio, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1673. Misbranding of thyroid tablets. U. S. v. 1,331 Bottles, 46 Bottles, and 205 Bottles of Thyroid Tablets. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15789. Sample Nos. 29397-H to 29400-H, incl., 29417-H to 29420-H, incl.)

LIBEL FILED: April 9, 1945, Northern District of California.

ALLEGED SHIPMENT: Between the approximate dates of January 21, 1944, and February 8, 1945, from Detroit, Mich., by Parke, Davis and Co.

PRODUCT: 1,331 100-tablet bottles, 46 500-tablet bottles, and 205 1,000-tablet bottles of *thyroid tablets* at San Francisco, Calif. Examination of samples showed that the product contained thyroid equivalent to approximately $1\frac{1}{2}$ times the grainage stated on the respective labels as calculated from the iodine content to the standard prescribed by the United States Pharmacopoeia.

LABEL, IN PART: "C. T. [or "C. C. T."] Thyroid Glands," and "Emplets Thyroid Gland."

NATURE OF CHARGE: Misbranding, Section 502(a), the statements on the labels of various portions of the article, " $\frac{1}{4}$ Grain," " $\frac{1}{2}$ Grain," "1 Grain," "2 Grains," and "5 Grains," were misleading because the quoted declarations created the impression that the article contained, respectively, the declared amounts of thyroid of the standard potency as specified in the United States Pharmacopoeia, whereas the article contained approximately $1\frac{1}{2}$ times the declared number of grains of thyroid of such standard potency; and such impression was not corrected by the label statements, "Thyroid Gland 50% Stronger than U. S. P.," or "Contains Desiccated Thyroid Gland 50% Stronger than U. S. P.," and "Contains 0.3% iodine," and (upon some of the labels) "Equivalent to $\frac{3}{8}$ gr. Thyroid U. S. P.," and "Equivalent to $7\frac{1}{2}$ grains Thyroid U. S. P."

Further misbranding, Section 502 (a), the label statement, "The high iodine content is obtained by careful selection of fresh glands," was false and misleading since the glands used were not selected but were the ordinary quality of glands as supplied generally by packing houses.

DISPOSITION: August 13, 1945. Parke, Davis and Co., Detroit, Mich., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for reprocessing or other lawful disposition under the supervision of the Federal Security Agency.

1674. Misbranding of granulated cramp bark. U. S. v. 7 Barrels of Granulated Cramp Bark. Consent decree of forfeiture. Product ordered released under bond. (F. D. C. No. 16261. Sample No. 24449-H.)

LIBEL FILED: June 4, 1945, Northern District of Texas.

ALLEGED SHIPMENT: On or about April 20, 1945, by J. L. Hopkins and Co., from New York, N. Y.

PRODUCT: 7 barrels of *granulated cramp bark* at Dallas, Tex. Examination showed that this product was maple bark and not cramp bark.

LABEL, IN PART: "Granulated Cramp Bark, so Called for Manufacturers Use."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation, "Cramp Bark, so Called" was false and misleading as applied to maple bark; and, Section 502 (e) (1), the label failed to bear the common or usual name of the article.

DISPOSITION: June 22, 1945. The First Texas Chemical Manufacturing Co., Dallas, Tex., having admitted the facts set forth in the libel, judgment of forfeiture was entered and the product was ordered released under bond to be relabeled and brought into compliance with the law, under the supervision of the Food and Drug Administration.

1675. Misbranding of Quits and Q-T Alternative—Nervine. U. S. v. 184 Bottles of Q-T Alternative—Nervine (and 2 other seizure actions against Quits and Q-T Alternative—Nervine). Default decrees of condemnation and destruction. (F. D. C. Nos. 16058, 16280. Sample Nos. 2650-H, 2651-H, 24138-H.)

LIBELS FILED: On or about April 30 and May 23, 1945, Northern District of Texas and Southern District of West Virginia.

ALLEGED SHIPMENT: Between the approximate dates of April 29, 1941, and October 7, 1944, by the Allied Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 184 bottles of Q-T Alternative—Nervine at Dallas, Tex., and 129 bottles of Quits and 70 bottles of Q-T Alternative—Nervine at Charleston, W. Va. Examination of samples showed that the product contained ammonium chloride, gold, sodium chloride, and water.

NATURE OF CHARGE: Q-T Alternative—Nervine, misbranding, Section 502 (a), the label statement "Alternative—Nervine" was false and misleading since the product was not an alternative and would have no effect on the nerves.

Quits, misbranding, Section 502 (a), the label statement, "Quits * * * The action of this product is such that it tends to mitigate the desire and craving for intoxicants," was false and misleading since the article was not effective in overcoming the desire or craving for intoxicants.

DISPOSITION: June 1 and 15, 1945. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1676. Misbranding of Starke Inhaler and Starke Inhalant. U. S. v. 24 Cartons and 142 Cartons of Starke Inhaler and Starke Inhalant. Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed. (F. D. C. Nos. 16382, 16694. Sample Nos. 31440-H, 31541-H.)

LIBELS FILED: June 16 and July 10, 1945, Southern District of California and Eastern District of Missouri.

ALLEGED SHIPMENT: On or about May 18 and June 11, 1945, by the Lewis E. Starke Pharmacal Co., from St. Louis, Mo. The shipment of June 11 was refused by the consignee and returned to the shipper on or about June 26, 1945.

PRODUCT: 24 cartons and 142 cartons of the above-named products at Inglewood, Calif., and St. Louis, Mo. Examination showed that each carton contained a glass inhaler; a bottle of a liquid consisting essentially of water, alcohol, glycerin, guaiacol, eucalyptol, menthol, and iodine; and a circular entitled "Facts About Starke Inhalant And The Starke Inhaler."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton label and in the circular were false and misleading since they represented and suggested that the article would be effective in the prevention and treatment of sinusitis, bronchitis, influenza, pneumonia, tonsillitis, bronchial asthma, la grippe, nasal catarrh, whooping cough, rose cold, and hay fever; and that its vapors were capable of destroying germs in the nose, throat, and chest. The article would not be effective in the prevention or treatment of the conditions stated and implied, and its vapors were not capable of destroying germs in the nose, throat, and chest.

DISPOSITION: July 14 and September 17, 1945. Charles J. Crafe of the Lewis E. Starke Pharmacal Co. having appeared as claimant for the Missouri lot and having admitted the misbranding of the product, and no claimant having appeared for the California lot, judgment of condemnation were entered. The California lot was ordered destroyed and the Missouri lot was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

1677. Misbranding of Ceregen. U. S. v. 100 Bottles of Ceregen. Default decree of condemnation and destruction. (F. D. C. No. 16059. Sample Nos. 113-H, 114-H.)

LIBEL FILED: April 25, 1945, Southern District of Florida.

ALLEGED SHIPMENT: On or about November 9, 1944, and January 13, 1945, by the Ulrici Medicine Co., Inc., from New York, N. Y.

PRODUCT: 100 bottles of Ceregen at Tampa, Fla. Examination of samples showed that the product consisted essentially of 9 percent of alcohol, 11 percent of nonvolatile matter, and approximately 80 percent of water. The nonvolatile matter included caffeine and compounds of iron and phosphorus. The total mineral matter was less than 1 percent, including 7.5 milligrams of iron and

174 milligrams of phosphorus per 100 milliliters, or 3.4 milligrams of iron and 78 milligrams of phosphorus per the recommended daily dose of 3 table-spoonfuls, for adults. Caffeine in the daily dose was 23 milligrams.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in an enclosed circular entitled "Ceregen" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of some, but not all, cases of physical exhaustion and nervous hyposthenia, general muscular weakness, irritability, and lack of appetite; that it would be efficacious as a tonic and as an aid to convalescence after an exhausting illness; that it would promote better nervous stability, greater physical energy, and increased vitality; that it would aid in supplying deficiencies of iron, phosphorus, and other salts; and that all of its ingredients were of the standard of purity and strength established by the United States Pharmacopoeia. The article would not be effective to fulfill the promises of benefit stated and implied, and some of the ingredients are not recognized by the United States Pharmacopoeia.

Further misbranding, Section 502 (a), the label statements, "A Well Balanced Medicinal Preparation * * * This product is compounded of the following ingredients per 100 cc.: Sod. Phosphate .876, Pot. Phosphate .292, Phosphoric Acid .286, Sod. Glycerophosphate .117, Pot. Glycerophosphate .189, S. Ext. of Kola (1-5) 1.752, S. Ext. of Dandelion (1-3) .076, Manganese Hypophosphite .011, Tr. Iron Citrochloride .174, Sod. Citrate .560, Glycerine 2.804, Alcohol 11.10," were misleading since they created the impression that the article possessed therapeutic value, whereas the article, if consumed in accordance with the directions on the label, "Dose: For Adults: One tablespoonful three times a day; for children over 12 years: One teaspoonful three times a day, to be taken before or after meals," would be essentially worthless as a therapeutic agent.

Further misbranding, Section 502 (a), the following statements in the circular were misleading since the composition of the article denominated "Ceregen" has not remained the same since 1896; it does not represent years of experimentation; and physicians and dietitians do not believe that the ingredients of the article have been combined with "balance," revealing deep knowledge of the properties and reactions of the alkaloids and phosphates in their relation to the human body: "When Dr. Charles J. Ulrici established the firm now bearing his name in the year 1896, it was with the thought of placing within reach of the average person the results of long years of experimentation in the pharmaceutical field. One of his best known formulas is that of Ceregen. Physicians and dietitians who have had occasion to study this formula believe Dr. Ulrici combined its ingredients with excellent balance, revealing deep knowledge of the properties and reactions of the alkaloids and phosphates in their relation to the human body."

DISPOSITION: June 20, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1678. Misbranding of fenugreek tea. U. S. v. 10 Dozen Cartons and 5 Dozen Cartons of Fenugreek Tea, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 16042. Sample No. 3049-H.)

LABEL FILED: April 18, 1945, District of Columbia.

PRODUCT: 10 dozen cartons, \$0.50 size, and 5 dozen cartons, \$1.50 size, of *fenugreek tea* which was being offered for sale in the District of Columbia by the Vita Health Food Co., Washington, D. C., together with a number of accompanying booklets entitled "Vita Health News" and placards entitled "Stomach Agony" and "Upset Stomach."

Examination disclosed that the product consisted essentially of fenugreek seeds.

LABEL, IN PART: "Lelord Kordel's Fenugreek tea Consists of Fenugreek Seeds * * * Lelord Kordel Products * * * Chicago."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and the designs of the stomach, kidney, liver, and intestinal tract, appearing in the booklets and placards, were false and misleading since the statements and designs represented and suggested that the article would be effective in the treatment of stomach agony, sour taste in the mouth, gas pains, upset stomach, liver and intestinal irritations, belching, colitis, ulcers, headaches, backaches,

a tired-out feeling, rheumatic and neuritic pains, and general physical debility; that it would flush out thick, stagnant bile; that it would assist in the flushing of the kidneys; that it would make the digestive organs feel sweet and clean; that it was equal in virtue to quinine for fevers; that it would decrease the nauseating and griping effects of purgatives; and that it would cleanse the bowels gradually. The article would not be effective for those purposes.

DISPOSITION: August 21, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1679. Misbranding of Nielsen Lactic Milk Whey and Nielsen Lactic Agar Whey. U. S. v. 55 Bottles of Nielsen Lactic Milk Whey and 20 Bottles of Nielsen Lactic Agar Whey, and 5,000 circulars. Consent decree of condemnation and destruction. (F. D. C. No. 16039. Sample Nos. 26451-H, 26452-H.)

LABEL FILED: On or about April 23, 1945, District of Colorado.

ALLEGED SHIPMENT: By the Nielsen Laboratories, Inc., from Elyria, Ohio. The drugs were shipped on or about January 9 and March 1, 1945, and the circulars were shipped on or about December 1, 1944.

PRODUCT: 55 bottles of *Nielsen Lactic Milk Whey*, 20 bottles of *Nielsen Lactic Agar Whey*, and 5,000 circulars at Denver, Colo. Various circulars were entitled: "Nielsen Health Products * * * Diabetes [or "Constipation," "Colitis," "Gastric Ulcers," "High Blood Pressure," "Dyspepsia & Gastritis," "Rheumatism & Arthritis," or "Hyperacidity & Dyspepsia"]." Other circulars were entitled: "Nielsen Lactic Milk Whey Aids Digestion," "Nielsen Lactic Milk Whey," "Nielsen Lactic Agar Whey," and "The pH in Colon Therapy."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular entitled "The pH in Colon Therapy" were false and misleading since they represented and suggested and created the impression that the *Milk Whey* would be effective in the treatment of constipation, in replacing *Bacillus acidophilus* therapy inducing an acid colon, and in ridding the intestinal tract of harmful bacteria, whereas the article would not be effective for such purposes.

Further misbranding, Section 502 (a), certain statements in the other circulars accompanying the articles were false and misleading since they created the impression that the *Milk Whey* and the *Agar Whey*, alone or in combination, would be effective in aiding digestion, in eliminating body poisons, and in promoting and maintaining good health; that they would be effective in retarding fermentation, gas production, and the formation of harmful bacteria or toxic poisons in the intestines; that they would be effective in the treatment of constipation, diabetes, colitis, gastric ulcers, high blood pressure or arteriosclerosis, low blood pressure, dyspepsia, indigestion, gastritis, rheumatism, arthritis, hyperacidity or acid stomach, diarrhea, and dysentery; and that they would act on the underlying causes of constipation and would rid the intestinal tract of harmful bacteria. The articles, alone or in combination, would not be effective for such purposes.

Further misbranding, Section 502 (a), the designation of the product, "Lactic Agar Whey for Constipation," was misleading since the article depended upon mineral oil for its laxative action.

DISPOSITION: June 25, 1945. The Nielsen Laboratories, Inc., having consented to the entry of a decree, judgment of condemnation was entered and the products, including the circulars, were ordered destroyed.

1680. Misbranding of Schrage's Medicine. U. S. v. 66 Packages of Schrage's Medicine. Default decree of condemnation and destruction. (F. D. C. No. 15293. Sample No. 96922-F.)

LABEL FILED: February 22, 1945, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about May 4, 1944, by the Frank Schrage Laboratories, Chicago, Ill.

PRODUCT: 66 packages, each package containing a bottle of a liquid preparation and an envelope containing pills. Analysis showed that the liquid consisted essentially of sodium salicylate, potassium iodide, sugar, alcohol, water, and extracts of plant drugs, including a laxative drug. The pills consisted essentially of mercury and laxative plant drugs.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels, envelopes, and in an accompanying circular, were false and misleading since they represented and suggested that the liquid medicine would

be effective in the treatment of rheumatic and neuralgic aches and pains, rheumatism, and gout; and that the combination of the liquid and pills would be effective in freeing the system from bile and in starting a natural action of the liver. The articles, either alone or in combination, would not be effective for the purposes claimed.

DISPOSITION: August 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1681. Misbranding of Pa-Poya. U. S. v. 12 Jugs and 5 Bottles of Pa-Poya. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 16127. Sample No. 2873-H.)

LABEL FILED: May 9, 1945, District of Columbia.

ALLEGED SHIPMENT: From Miami, Fla., by the Tropical Fruits Laboratory.

PRODUCT: 12 1-gallon jugs of *Pa-Poya*, together with a quantity of the same product repacked from gallon containers into 4 1-quart bottles and 1 1-pint bottle. The product was offered for sale while in possession of the Citrus Juice Co., Washington, D. C.

Examination showed that the product was a clear liquid having an artificial fruit-type flavor and a burning taste, containing not more than 4 milligrams of vitamin C per ounce, and possessing no digestive properties.

NATURE OF CHARGE: Misbranding (12-jug lot), Section 502 (a), the label statements which represented and suggested that the article would be effective in the treatment, relief, or correction of indigestion, gastric disorders, irritated throat, childrens disorders, "morning after" disaster, stomach disorders, sore throats, eczema, acidosis, and many other ailments, were false and misleading since the article would not be effective in the treatment, relief, or correction of those conditions and diseases.

Misbranding (repacked lot), Section 502 (a), the statements appearing on the labels furnished by the shipper and attached to the bottles containing the article, "A Tropical Fruit Beverage Concentrate containing the entire Papaya—pulp, * * * skin and seed * * * As an aid to digestion or gastric disturbance," were false and misleading since the article did not contain the pulp, skin, or seeds of papaya, and it would not be effective as an aid to digestion or gastric disturbances.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 8299.

DISPOSITION: August 21, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution.

1682. Misbranding of vitamin B complex tablets and vitamin and mineral tablets. U. S. v. 76 Packages of Vitamin B Complex Tablets, etc. Default decree of condemnation and destruction. (F. D. C. No. 16285. Sample Nos. 6327-H, 6328-H.)

LABEL FILED: May 29, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about January 19, 1945, by the City Food Mart, Fort Atkinson, Wis.

PRODUCT: 76 packages of *vitamin B complex tablets*, 119 packages of *vitamin B complex with added thiamine*, and 55 packages of *vitamin and mineral tablets* at New York, N. Y.; also approximately 50 leaflets entitled "Buoyant Health for All the Family," 50 leaflets entitled "For Your Health's Sake," 6 display racks entitled "Feel Fit as a Major," and 12 circular display cards entitled "Ask for Major-B Brand."

LABEL, IN PART: "Major-B Natural Vitamin B Complex Tablets [one lot further labeled, "with Added Thiamine"]"; "Major Vitamins and Minerals Vitamins A, B, D with Calcium, Phosphorus, Iron."

NATURE OF CHARGE: *Vitamin B complex tablets* and *vitamin B complex tablets with added thiamine*, misbranding, Section 502 (a), certain statements in accompanying leaflets entitled "Buoyant Health for All the Family" and "Vitamins for Victory," and on the display racks, were false and misleading since they created the impression that the articles would be effective to provide greater energy, steadier nerves, better digestion, improved health and vigor, better appetite, insurance from vitamin deficiencies, physical well-being, and protection against frequent colds, constipation, fatigue, digestive upsets, and other com-

mon ills; that the articles would provide the vitamins found in whole wheat bread, eggs, milk, liver, and tomato juice; that they contained nutritionally significant amounts of all vitamins of the B complex; that there are widespread dietary deficiencies that would be corrected by the use of the articles; that ordinary foods are unreliable sources of vitamins; and that it is desirable, if not necessary, to supplement the ordinary diet with such vitamins. The articles would not fulfill the promises of benefit stated and implied; and it is not true that there are widespread dietary deficiencies that would be corrected by use of the articles, and that ordinary foods are unreliable sources of vitamins.

Vitamin and mineral tablets, misbranding, Section 502 (a), certain statements in the leaflet entitled "For Your Health's Sake" were false and misleading since they created the impression that the article would be effective to provide vigor, health, and energy; that it would build resistance to colds, prevent fatigue, and be effective in the treatment and prevention of nervousness, improper digestion, poor appetite, loss of weight, constipation, night blindness, premature aging, and poor teeth and gums; that the article would be effective to provide the vitamins and minerals found in eggs, milk, chicken, cabbage, and cottage cheese; and that foods are unreliable sources of vitamins, and therefore it is desirable, if not necessary, to supplement the diet with the article. The article would not be effective for the purposes stated; there are no widespread dietary deficiencies that would be corrected by the use of the article; the article would not supply the vitamins and minerals found in the foods named; and furthermore, foods are reliable sources of vitamins and minerals.

The articles were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

DISPOSITION: June 20, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1683. Misbranding of Pure Soy Bean Oil Lecithin, Food Oils, High Potency Vitamin B Complex Tablets, and Blendavita. U. S. v. 3 Bottles of Pure Soy Bean Oil Lecithin, 13 Bottles of Food Oils, 10 Bottles of High Potency Vitamin B Complex, 21 Packages of Blendavita, and a number of leaflets. Default decree of condemnation and destruction. (F. D. C. No. 16286. Sample Nos. 28381-H to 28384-H, incl.)

LABEL FILED: May 25, 1945, Western District of Washington.

ALLEGED SHIPMENT: From Los Angeles, Calif., by Ruth Clark Products. The products were shipped on or about March 9, 1945, and the leaflets were shipped on or about March 1, 1945.

PRODUCT: 3 13-ounce bottles of *Pure Soy Bean Oil Lecithin*, 13 8-ounce bottles of *Food Oils*, 10 100-tablet bottles of *High Potency Vitamin B Complex*, 21 12-ounce packages of *Blendavita*, and approximately 40 leaflets entitled "Ruth Clark Products," at Tacoma, Wash.

Examination disclosed that the *Pure Soy Bean Oil Lecithin* was essentially a mixture of oil, such as soy bean oil, and partially refined sugar sirup; that the *Food Oils* was a mixture of vegetable oils, including cottonseed and sesame oils; that the *High Potency Vitamin B Complex Tablets* consisted essentially of yeast, starch, kaolin, and very small amounts of dried parsley, dried kelp, dried dandelion leaf, and other organic matter, and contained, per tablet, 23.8 milligrams of iron, or 2.20 grains of iron per 6 tablets; and that the *Blendavita* consisted essentially of coarsely ground alfalfa leaves and stems, mixed with the powdered stems of a species of Ephedra.

NATURE OF CHARGE: *Pure Soy Bean Oil Lecithin*, misbranding, Section 502 (a), certain statements in the leaflets were false and misleading since they represented and suggested that lecithin is a substance essential in the nutrition of man; that ordinary diets supply an inadequate amount of lecithin; and that the article would be effective to correct or prevent lassitude, slackness, nervousness, insomnia, debility, and improper nerve functioning. Lecithin is not a substance essential in the nutrition of man; ordinary diets supply an adequate amount of lecithin; and the article would not be effective to correct or prevent the conditions and symptoms mentioned.

Food Oils, misbranding, Section 502 (a), the following statements in the leaflet were false and misleading since they represented and suggested that the article would be effective to aid in the digestive processes, whereas the article would not be effective for such purpose: "Your automobile needs lubricating. What about your body? * * * They furnish valuable food oils

used and needed by the digestive processes * * * notice the beneficial results to your general digestive process."

High Potency Vitamin B Complex, misbranding, Section 502 (a), certain statements in the leaflet were false and misleading since they represented and suggested that the article would be effective to prevent or correct gas formation, colitis, constipation, diarrhea, tiredness, lack of endurance, and impaired digestion of sugar and starches; and that it would be effective to correct anemia. The article would not be effective for such purposes.

Blendavita, misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since they represented and suggested that the article would be effective to soothe, whereas it would not be effective for such purpose: (Package label) "soothing and relaxing to tense, fatigued nerves"; (leaflet) "Soothing to tired taut nerves."

The *Pure Soy Bean Oil Lecithin* was also alleged to be misbranded and the *High Potency Vitamin B Complex* was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 8298.

DISPOSITION: August 21, 1945. No claimant having appeared, judgment of condemnation was entered and the products, including the leaflets, were ordered destroyed.

1684. Misbranding of Ritamine Capsules. U. S. v. 479 Packages of Ritamine Capsules and a quantity of printed matter. Default decree of condemnation. Product ordered delivered to a public institution. (F. D. C. No. 16043. Sample No. 2856-H.)

LABEL FILED: April 18, 1945, District of Columbia.

PRODUCT: 144 150-capsule packages, 260 70-capsule packages, and 75 20-capsule packages of *Ritamine Capsules* offered for sale by the Vita Health Food Co., at Washington, D. C., together with a number of accompanying booklets entitled "Vita Health News" and leaflets entitled "This Box of Ritamine" and "American Dietaids Company, Inc., Yonkers, N. Y."

Examination showed that the product consisted of black capsules and brown capsules. The black capsules contained various vitamins, including vitamin A, vitamin B₁, vitamin B₂, vitamin C, and niacinamide. The brown capsules contained various mineral salts, including calcium, phosphorus, iodine, and iron compounds.

LABEL, IN PART: "American Dietaids' Ritamine * * * Vitamin and Mineral Capsules * * * American Dietaids Company, Inc., Yonkers, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the booklet entitled "Vita Health News" were false and misleading since the article would not fulfill the promises of benefit stated and implied by them: "Vitamins shortage Colds Sinusitis Watch out if you don't get enough Vitamin A and you have a sensitive membrane of your nose, throat, bronchial tubes or sinuses. Sore throat, colds, or sinus involvement may frequently follow. All the Vitamin A you probably need, together with 8 other vitamins and 9 important minerals, are now concentrated into 2 amazing Ritamine Capsules. This is truly a wonder of modern science. * * * Once a day, any time you think of it, you take your 2 tiny Ritamines for this vitamin-mineral insurance."

Further misbranding, Section 502 (a), certain statements and designs appearing in the leaflet were misleading since they represented and suggested and created the impression that the article would supply eight vitamins and nine minerals of nutritional importance; that it is difficult, if not impossible, to obtain sufficient vitamins and minerals from a diet of common foods; and that the use of the article would prevent or correct the following conditions: Loss of ability to resist infections, particularly of the ears, eyes, nose, and sinus; unsatisfactory functioning of glands; inability of expectant mothers to nourish the embryonic baby; dryness and scaliness of the skin and loss of its sensitivity to touch; loss of ability to see clearly in a dim light; failure of the muscles of the stomach and intestines to function normally; failure to satisfactorily burn the starch and sugar in the food one eats and turn them into required body fuel; loss of appetite; inability of food to oxidize properly in the tissues; tendency of the blood capillaries to become fragile and bleed; pain around the joints; loose and decayed teeth; failure of nerve impulses to be properly transmitted to the muscles, causing a jumpy nervous

system; faulty heart rhythm; failure of the blood to clot well; kidney stones, poor bones, and decaying teeth; loss of tissue tone and unhealthy condition of the skin; digestive disturbances and a tendency toward colitis; cataract, loss of hair, and unhealthy loss of weight; and imperfectly formed and maintained tooth enamel. The article would not supply eight vitamins and nine minerals of nutritional importance; it is not difficult or impossible to obtain sufficient vitamins and minerals from a diet of common foods; and the use of the article would not prevent or correct the diseases, abnormalities, and symptoms stated and implied in the leaflets.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: August 21, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a public institution.

1685. Misbranding of Merilla Shampoo. U. S. v. 305 Dozen Bottles of Merilla Shampoo and 500 circulars. Consent decree of condemnation and destruction. (F. D. C. No. 16299. Sample No. 13043-H.)

LIBEL FILED: May 31, 1945, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 19, 1945. This lot of goods had been shipped originally by An-Ne's Products Co., from Scranton, Pa., to the G. C. Murphy Co., Indianapolis, Ind., and was returned by the latter firm.

PRODUCT: 125 dozen 2-ounce bottles, 147 dozen 16-ounce bottles, and 32 dozen 32-ounce bottles of *Merilla Shampoo* and 500 circulars entitled "The Charm of Beautiful Healthy Hair," at Scranton, Pa.

The shampoo consisted essentially of soap, water, and not more than 0.3 percent of other ingredients, including plant material.

LABEL, IN PART: (Bottles) "Merilla Shampoo A Natural Beautifier * * * Manufactured by An-Ne's Products Co. * * * Scranton 10, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the article was a tonic; that it would be effective to promote hair health and to maintain a clear skin, free from eruptions and wrinkles, and that it would be effective in the prevention or treatment of dandruff, falling hair, and baldness. The article was not a tonic, and it would not be effective for the purposes claimed.

Further misbranding, Section 502 (a), certain statements on the bottle labels and in the circulars were misleading since they represented and suggested that the article was not a soap shampoo, whereas it was a soap shampoo.

DISPOSITION: July 2, 1945. The owner of the product having consented to the entry of a decree, judgment of condemnation was entered and the product, including the circulars, was ordered destroyed.

1686. Misbranding of Beautician's Mange Treatment. U. S. v. 22 Bottles of Beautician's Mange Treatment, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 16072. Sample No. 31212-H.)

LIBEL FILED: May 11, 1945, Southern District of California.

ALLEGED SHIPMENT: From Chicago, Ill., by the American Beauty Products Co. The bottles were shipped on or about May 2, 1945. The date of shipment of the printed matter was alleged to be unknown.

PRODUCT: 22 bottles of *Beautician's Mange Treatment* and 4 accompanying catalogs entitled "City Catalog No. 80" or "City Catalog No. 81," at Los Angeles, Calif. Examination showed that the product consisted essentially of mineral oil and guaiacol.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling statements, (bottle label) "For the treatment of dandruff and falling hair. With vigorous massage this preparation will improve circulation in the scalp and thus aid in reducing falling and breaking of hair," and (catalog) "Falling, breaking hair can be reduced and scalp circulation improved when this preparation is used with vigorous massage for a few moments each week," were false and misleading since the article would not be effective in the treatment of dandruff or falling or breaking hair, and it would not improve the circulation in the scalp; and,

Section 502 (e), the label of the article failed to bear the common or usual name of each active ingredient.

It was also alleged that another article, *American Calcium Pantothenate*, was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 8295.

DISPOSITION: June 5, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE*

1687. Misbranding of Ger-Mo-Kill Wormer & Water Disinfect, Ger-Mo-Kill Sheep and Lamb Bar, and Hog Wormer and Conditioner. U. S. v. Robert S. Cox (Ger-Mo-Kill Chemical Co.). Plea of guilty. Fine, \$300 and costs. (F. D. C. No. 15511. Sample Nos. 8499-F, 8500-F, 8619-F.)

INFORMATION FILED: May 25, 1945, Southern District of Iowa, against Robert S. Cox, trading as the Ger-Mo-Kill Chemical Co., Colfax, Iowa.

ALLEGED SHIPMENT: Between the approximate dates of October 28, 1943, and January 18, 1944, from the State of Iowa into the State of Minnesota.

PRODUCT: Analyses disclosed that the *Wormer & Water Disinfect* consisted essentially of naphthalene and small portions of epsom salt, copper sulfate, kamala, nicotine, 0.02 percent, formaldehyde, and creosote; that the *Sheep and Lamb Bar* consisted essentially of naphthalene and small proportions of phenothiazene, 0.56 percent, epsom salt, copper sulfate, and sodium bicarbonate; and that the *Hog Wormer and Conditioner* consisted essentially of epsom salt, copper sulfate, naphthalene, formaldehyde, and small proportions of creosote and oil of chenopodium.

NATURE OF CHARGE: *Wormer and Water Disinfect*, Misbranding, Section 502 (a), certain statements on the label and in accompanying circulars entitled, "The Benefits of Ger-Mo-Kill Poultry Bars" and "How to Use Ger-Mo-Kill Poultry Bars," were false and misleading since they represented and suggested that the article possessed germicidal and worm-expelling properties and was a water disinfectant; that it would be effective in the prevention in poultry of coccidiosis, roup, bronchitis, colds, and intestinal infections; that it would be effective in the removal of roundworms, capillaria, pinworms, and tapeworms; that it would be effective in maintaining health and egg production in chickens and turkeys; that it would be effective in preventing worm infestation and blackhead in turkeys and in preventing the spread of coccidiosis, colds, and bronchitis in baby chicks; and that, when administered to fowls, it would destroy worm-eggs, and when administered to baby chicks, it would be effective in preventing worms and would aid in the production of healthy and vigorous pullets. The article did not possess germicidal and worm-expelling properties; it was not a water disinfectant; and it would not be effective for the purposes represented.

Sheep and Lamb Bar, misbranding, Section 502 (a), certain statements on the label and in an accompanying circular entitled "Ger-Mo-Kill Sheep Bar" were false and misleading since they represented and suggested that the article possessed germicidal properties; that it would be effective in the elimination and removal of stomach and nodular worms in sheep and lambs; that it would be effective in preventing worms in sheep and lambs and in producing good and large lambs; and that it would be effective as a conditioner for ewes. The article did not possess germicidal properties, and it would not be effective for the purposes represented.

Hog Wormer and Conditioner, misbranding, Section 502 (a), certain statements on the label and in accompanying circulars entitled "Benefits of Ger-Mo-Kill Pig and Hog Bars" were false and misleading since they represented and suggested that the article possessed germicidal properties and would be effective as a conditioner; that it would be effective in the removal and destruction of worms in pigs and hogs and in the prevention and treatment of necro and flu in pigs and hogs; that it would be effective in preventing and treating practically all pig trouble and numerous diseases in pigs and hogs; that it would be effective as a conditioner for brood sows; and that it would aid in the production of good, large litters of healthy pigs. The article did not possess germicidal properties, and it would not be effective for the purposes represented.

*See also No. 1665.

DISPOSITION: October 19, 1945. A plea of guilty having been entered, the court imposed a fine of \$100 on each of the 3 counts, a total fine of \$300, plus costs.

1688. Misbranding of Sep-Tone. *U. S. v. Donald D. Dolan (Dolan Laboratories).* Plea of *nolo contendere*. Fine, \$200. (F. D. C. No. 15492. Sample Nos. 72064-F, 89736-F.)

INFORMATION FILED: May 7, 1945, Eastern District of Missouri, against Donald D. Dolan, trading as the Dolan Laboratories, St. Louis, Mo.

ALLEGED SHIPMENT: On or about June 24 and October 6, 1944, from the State of Missouri into the State of Illinois.

PRODUCT: Analysis disclosed that the product consisted essentially of water, with small amounts of potassium dichromate; sodium, zinc, and copper sulfo-carbolates; ammonium chloride, and an iodide.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the article, "Sep-Tone," was misleading since it represented and created the impression that the article would be an efficacious treatment for septic conditions in poultry, and that it would improve the tone of poultry. The article would not be efficacious for such purposes.

Further misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be efficacious in the treatment of septic conditions in poultry and rabbits; that it would be efficacious to improve the tone of poultry; that it would be efficacious in the cure, mitigation, treatment, and prevention of enteritis, mycosis, cholera, typhoid, colds, coccidiosis, bronchitis, and other bacterial infections; that it would be efficacious in the treatment of fowls out of condition; and that, in the dilution recommended, it possessed antiseptic properties. The article would not be efficacious for the purposes claimed, and it was not an antiseptic in the dilution recommended.

DISPOSITION: October 16, 1945. A plea of *nolo contendere* having been entered, the court imposed a fine of \$100 on each count, a total fine of \$200.

1689. Misbranding of Illinois Special Sheep Medicine and Illinois Sun Rise Concentrate. *U. S. v. 50 Bags of Illinois Special Sheep Medicine and 6 Bags of Illinois Sun Rise Concentrate.* Consent decree of condemnation. Products ordered released under bond. (F. D. C. No. 15810. Sample Nos. 22522-H, 22523-H.)

LABEL FILED: On or about April 16, 1945, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about January 30, 1945, by the Illinois Manufacturing Co. of Quincy, Quincy, Ill.

PRODUCT: 50 100-pound bags of *Illinois Special Sheep Medicine* and 6 100-pound bags of *Illinois Sun Rise Concentrate* at Lancaster, Mo.

Analyses of samples disclosed that the *Sheep Medicine* consisted essentially of mineral constituents, including 37 percent of salt, tobacco dust, limestone, charcoal, iron sulfate, and small amounts of copper and phosphate, and no potassium iodide; and that the *Concentrate* consisted essentially of plant material, including 20 percent of protein, bran, charcoal, calcium carbonate, soda, sugars, iron oxide, copper sulfate, and yeast.

NATURE OF CHARGE: *Sheep Medicine*, misbranding, Section 502 (a), the following statements in the labeling were false and misleading since the article contained no potassium iodide; it would not assist nature in keeping animals healthy; and it was not effective in the prevention or treatment of stomach worms in sheep and goats: (Bag) "Formula * * * Potassium Iodide"; (circular entitled "Illinois Sheep Medicine (Feed as Directed)") "Assist nature in keeping the animal healthy"; "Under ordinary conditions your sheep and goats should not need drenching for stomach worms where Illinois Sheep Medicine is fed regularly"; "Potassium Iodide."

Concentrate, misbranding, Section 502 (a), the following statements in the labeling were false and misleading since the article would not make oats and wheat more digestible; it was not a substitute for sunshine; it would not enable animals to digest and assimilate nutrients in feed that otherwise would be wasted; it would not furnish minerals essential for digestion, promote vitality, or insure faster growth and development and lower feeding costs; and it was not effective in the treatment of coccidiosis: (Circular entitled "Illinois Sun Rise Concentrate Open Formula") "oats and wheat * * * when Sunrise Concentrate is added, becomes more digestible"; "Sunrise Concentrate contains

yeast, which means sunshine added to the feed that goes into the system of the hog—or other animal”; “Sunrise Concentrate if used properly will enable animals to digest and assimilate nutrients in feed that would otherwise be wasted”; “It furnishes * * * the minerals essential for digestion”; “Promotes vitality and insures faster growth and development”; “Lowers feeding costs”; “Coccidiosis yields to fermented mash feeds”; “In case this disorder is affecting the flock feed fermented mash three times a day for a week and then twice a day.”

DISPOSITION: May 28, 1945. The Illinois Manufacturing Co. of Quincy, claimant, having admitted that the products were misbranded, judgment of condemnation was entered and the products were ordered released under bond, conditioned that the *Sheep Medicine* be reprocessed by adding potassium iodide in an amount to comply with the label, and that the circulars relating to both products be destroyed, under the supervision of the Federal Security Agency.

1690. Misbranding of Victor Wheat Germ Oil. U. S. v. 501 Bottles and 28 Jugs of Victor Wheat Germ Oil, and a number of circulars. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15811. Sample No. 19112-H.)

LABEL FILED: April 13, 1945, Western District of Wisconsin.

ALLEGED SHIPMENT: By the Sunland Manufacturing Co., from Minneapolis, Minn. The product was shipped between the approximate dates of January 9 and March 20, 1945. A portion of the circulars were packed in the shipping containers of the product, and the remainder were shipped separately in January 1945.

PRODUCT: 501 bottles and 28 jugs of *Victor Wheat Germ Oil* at Marshfield, Wis., together with 500 circulars entitled “Sending Shy Breeders to Slaughter is out of Style!” and 100 circulars entitled “Victor Wheat Germ Oil A nutritional aid to breeding stock and poultry.”

Examination of a sample disclosed that the product was a golden amber oil with a wheat-like odor, such as wheat germ oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the circulars were false and misleading since they represented and suggested that the article would be effective in preventing or correcting breeding difficulties in the cases of dairy cows, bulls, mares and studs, sows and boars, ewes and rams, foxes, mink, chickens, and turkeys; that it would keep stock in top breeding condition; that use of the article would restore sires to normal productive service; that it would increase the litter average, promote greater hatchability of eggs, and result in healthier birds, calves, foals, and pigs; and that the article would save valuable breeding stock. The article would not be effective in preventing or correcting breeding difficulties in the various species of animals named, and it would not be effective to fulfill the promises of benefit suggested and implied.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: August 14, 1945. The Sunland Manufacturing Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

1691. Misbranding of Acidox and Germozone. U. S. v. 90 Bottles of Acidox, 125 Bottles of Germozone, and 75 catalogs. Default decree of condemnation and destruction. (F. D. C. No. 15990. Sample Nos. 12802-H, 12803-H.)

LABEL FILED: May 3, 1945, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 16, 1945, by the George H. Lee Co., from Omaha, Nebr.

PRODUCT: 90 bottles of *Acidox*, 125 bottles of *Germozone*, and 75 catalogs entitled “The Lee Way Poultry Book, 1944,” at Cincinnati, Ohio.

Examination disclosed that the *Acidox* consisted essentially of water, salt, acetic acid, sodium bisulfate, zinc chloride, and a small amount of pyridine; and that the *Germozone* consisted essentially of water, salt, aluminum sulfate, potassium permanganate, and potassium chlorate.

NATURE OF CHARGE: *Acidox*, misbranding, Section 502 (a), certain statements and designs on the bottle labels and in the catalog were false and misleading since they represented and suggested that the article, when used as directed,

would be an effective treatment or preventive of coccidiosis of poultry and rabbits; and that it would be effective to control protozoan parasites and parasitic worms. The article, when used as directed, would not be effective for the purposes claimed.

Germozone, misbranding, Section 502 (a), certain statements and designs on the bottle labels and in the catalogs were false and misleading since they represented and suggested that the article, by reason of its germicidal or bactericidal properties, would be effective, when used in the drinking water as directed, to successfully combat disease conditions of poultry and livestock caused by germs, and to prevent the transmittal of such diseases; that the article would be effective, when used as directed, in the treatment and prevention of coccidiosis, diarrhea, bowel troubles, and other serious disease conditions of poultry; that it would be effective in the treatment of scours, necrotic enteritis, and other disease conditions of calves, pigs, and other livestock; and that, by reason of its astringent action, it would be effective to combat diseases of the digestive tract of fowls and other animals. The article would not be effective for such purposes.

DISPOSITION: May 31, 1945. No claimant having appeared, judgment of condemnation was entered and the products, including the catalogs, were ordered destroyed.

1692. Misbranding of Stop-Bloat Chemicals. U. S. v. 29 Packages of Stop-Bloat Chemicals (and 3 other seizure actions against Stop-Bloat Chemicals). Default decrees of condemnation and destruction. (F. D. C. Nos. 16111, 16339, 16632, 16633. Sample Nos. 26586-H to 26588-H, incl., 33143-H.)

LIBELS FILED: Between May 9 and June 22, 1945, Districts of Kansas, Montana, and Idaho.

ALLEGED SHIPMENT: Between the approximate dates of November 13, 1944, and May 22, 1945, by the Hy-Life Mineral Co., from Denver, Colo.

PRODUCT: *Stop-Bloat Chemicals*, 29 packages at Atwood, Kans., 23 packages at Dillon, Mont., 22 cartons at Twin Falls, Idaho, and 23 cartons at Caldwell, Idaho.

Examination showed that the product consisted essentially of ammonium chloride, potassium chlorate, calcium carbonate, sodium sulfate, iron oxide, and a small amount of anise, sand, and plant material, including tobacco.

LABEL, IN PART: "Blake's Stop-Bloat Chemicals."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements and design on the label of the carton and in an accompanying circular were false and misleading since they represented and suggested that the article, when used as directed, would be effective in the prevention of bloating of livestock. The article, when used as directed, would not be effective for such purpose.

DISPOSITION: Between June 23 and September 5, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1693. Misbranding of Far-Vet Merco-Tabs No. 2, Gwyo-Dine Poultry Solution Tablets, and Gwyo-Spray. U. S. v. 14 Bottles of Merco-Tabs No. 2, 4 Bottles of Gwyo-Dine Poultry Solution Tablets, 9 Bottles of Gwyo-Spray, and a printed leaflet. Default decree of condemnation. Product ordered disposed of by the United States marshal. (F. D. C. No. 16135. Sample Nos. 18345-H to 18347-H, incl.)

LIBEL FILED: May 16, 1945, District of South Dakota.

ALLEGED SHIPMENT: By the Farmers Veterinary Supply Co., from St. Paul, Minn. The drugs were shipped between the approximate dates of December 20, 1944, and March 16, 1945, and the leaflet was shipped during the fall of 1944.

PRODUCT: 14 100-tablet bottles of *Merco-Tabs No. 2*, 4 100-tablet bottles of *Gwyo-Dine Poultry Solution Tablets*, 9 8-ounce bottles of *Gwyo-Spray*, and a leaflet described as "Dealers' Price List 1944," at Dell Rapids, S. Dak.

Examination disclosed that the *Merco-Tabs No. 2* consisted essentially of mercury bichloride, zinc sulfocarbolate, sodium citrate and carbonate, and a blue coloring matter; that the *Gwyo-Dine Poultry Solution Tablets* consisted essentially of potassium dichromate, iodine, creosote, potassium gualacolsulfonate, and salt; and that the *Gwyo-Spray* consisted essentially of creosote, thymol, phenol, turpentine, iodine, camphoraceous substances, and mineral oil.

NATURE OF CHARGE: *Merco-Tabs No. 2*, misbranding, Section 502 (a), certain statements on the label and in the accompanying leaflet were false and misleading since they represented and suggested that the article was an adequate treatment for cholera, typhoid, coccidiosis, and other disease conditions of fowls, whereas the article would not be effective for such purposes.

Gwyo-Dine Poultry Solution Tablets and *Gwyo-Spray*, misbranding, Section 502 (a), certain statements on the labels and in the accompanying leaflet were false and misleading since they represented and suggested that the articles, when used as directed, would be effective to treat roup, colds, and other respiratory diseases of poultry, whereas the articles would not be effective for such purposes.

DISPOSITION: June 19, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered to be disposed of by the United States marshal, in accordance with the law. The products were destroyed.

1694. Misbranding of Kama-Nico and Far-Vet Alkules, Merco-Tabs No. 2, Gwyo-Dine, and Gwyo-Spray. U. S. v. 237 Bottles of *Kama-Nico*, 197 Cans of *Far-Vet Alkules*, 158 Packages of *Far-Vet Merco-Tabs No. 2*, 730 Bottles of *Far-Vet Gwyo-Dine*, 415 Bottles of *Far-Vet Gwyo-Spray*, and a number of circulars. Consent decrees of condemnation. Products ordered released under bond. (F. D. C. Nos. 16145, 16151. Sample Nos. 18561-H to 18565-H, incl.)

LIBELS FILED: May 26 and June 1, 1945, District of Minnesota.

ALLEGED SHIPMENT: The drugs were shipped between the approximate dates of July 13, 1943, and September 23, 1944, from Kansas City, Mo., by Research Products, Inc.

PRODUCT: 237 100-tablet bottles of *Kama-Nico*, 197 5-pound cans of *Alkules*, 130 100-tablet packages and 28 1,000-tablet packages of *Merco-Tabs No. 2*, 730 100-tablet bottles of *Gwyo-Dine*, and 415 8-ounce bottles of *Gwyo-Spray* at St. Paul, Minn., together with a number of circulars entitled "Dealers' Price List 1944" and "Price List 1944," which accompanied certain lots of the drugs.

Examination disclosed that the *Kama-Nico* contained nicotine sulfate, kamala extractives equivalent to not more than 2.85 grains of powdered kamala per tablet, and 0.49 grain of calomel per tablet; that the *Alkules* consisted essentially of sodium hydroxide, carbolic acid, and small proportions of sodium carbonate, copper sulfate, and sodium hyposulfite; that the *Merco-Tabs No. 2* consisted essentially of 8 grains of mercury bichloride per tablet, zinc sulfo-carbolate, sodium citrate and carbonate, and blue coloring matter; that the *Gwyo-Dine* consisted essentially of potassium dichromate, iodine, creosote, potassium guaiacolsulfonate, and salt; and that the *Gwyo-Spray* consisted essentially of cresote, camphoraceous substances, thymol, phenol, turpentine, and iodine, in an oil base.

LABEL, IN PART: "Far-Vet Alkules [or "Merco-Tabs No. 2—Gallon Size," "Gwyo-Dine," or "Gwyo-Spray"] * * * Distributed by Farmers Veterinary Supply Co., St. Paul, Minnesota," or "Kama-Nico."

NATURE OF CHARGE: *Kama-Nico*, misbranding, Section 502 (a), the label statements, "Give 1 tablet to chicks weighing from 1½ to 3 lbs. Prepare birds by withholding feed for 12 to 24 hours. Six hours afterwards birds may have a liberal amount of Epsom Salts dissolved in water; 2-oz. to a gallon of water * * * Do not worm sick or emaciated birds," were false and misleading since they represented and suggested that the article, when used as directed, would be effective to remove worms from poultry, whereas it would not be effective in the treatment for any species of worms which infest poultry. Further misbranding, Section 502 (a), the name of the article, "Kama-Nico," was false and misleading since the designation implied that the article contained only the active ingredients kamala and nicotine, whereas the article also contained calomel as an active ingredient; and the label statement, "Each Tablet Contains: Powdered Extract Kamala . . . 2.50 grs. (equal in drug strength to 7.50 grs. (Powdered Kamala))," was false and misleading since the article did not contain 2.5 grains of kamala extract equivalent to 7.5 grains of powdered kamala. Further misbranding, Section 502 (e), the article contained calomel and its label failed to state that calomel is a derivative of mercury.

Alkules, misbranding, Section 502 (a), the following label statements were false and misleading since they represented and suggested that the article would be effective in the treatment of sick animals, such as hogs, whereas the article would not be effective in the treatment of any disease condition affecting hogs or other animals: "Directions Dissolve each pound (2 cupfuls) of the powder in a gallon of soft water. If clear solution is desired, filter or allow to stand overnight and draw off clear liquid. Add one pint of this solution to 15 gallons of water in which 1 pound of common salt has been added. Soak 3 bushels of oats in this solution for at least 12 hours. Feed to capacity for a week or ten days, feeding nothing else during this period and allow plenty pure drinking water. Isolate sick animals and keep hogs in dry, comfortable quarters."

Merco-Tabs No. 2, misbranding, Section 502 (a), the following label statements were false and misleading since they represented and suggested that the article would be of value in the prevention or treatment of diseases of poultry, whereas the article would not be of value for such purposes: "For drinking water medication * * * Directions Dissolve 1 tablet in 1 gallon of drinking water. In aggravated cases use 2 tablets to 1 gallon of water. Allow no other water. At the first sign of an outbreak—isolate all infected birds in separate pen or house to avoid spreading the disease among the rest of the flock. Begin treatment immediately, continuing for about a week and repeating thereafter as indicated." Further misbranding, Section 502 (a), the statements in the circulars, "For fowl cholera, typhoid, coccidiosis, and blackhead in poultry. One tablet dissolved in a gallon of water will make the best intestinal disinfectant for poultry," and "For Fowl Cholera, Typhoid and Coccidiosis," were false and misleading since the article, when used as directed, would have no value in the treatment or prevention of fowl cholera, typhoid, coccidiosis, or blackhead in poultry, nor would it be effective as an intestinal disinfectant.

Guyo-Dine, misbranding, Section 502 (a), the label statement, "Poultry Solution Tablets," was false and misleading since it represented and suggested that the article, when used as directed, would be of therapeutic value in the treatment of poultry, whereas the article, when used as directed, possessed no therapeutic value in the treatment of poultry; and the statement, "For Roup, Colds, and All Respiratory Ailments," appearing in the circular entitled "Dealer's Price List 1944," was false and misleading since the article would not be effective in the treatment of roup, colds, and respiratory diseases of fowls.

Guyo-Spray, misbranding, Section 502 (a), the following label statements were false and misleading since they represented and suggested that the article would be effective in the treatment of diseases of the respiratory tracts of fowls, whereas the article would not be effective for such purposes: "Spray Application for Poultry * * * Directions Fill atomizer or spray gun with undiluted Guyo-Spray and spray nostrils, around the eyes and down the throat of all birds. Birds should then be placed in separate pen or house to avoid contact with healthy birds. May also be used in drinking water; 1 tablespoon to each gallon of water." Further misbranding, Section 502 (a), the statement, "For Roup, Colds and Brooder Pneumonia," appearing in the circular entitled "Dealers' Price List 1944," was false and misleading since it represented and suggested that the article would be effective in the treatment of respiratory diseases of poultry, whereas the article would not be effective for such purpose.

DISPOSITION: July 19, 1945. Joseph Pogoriler, trading as the Farmers Veterinary Supply Co., claimant, having consented to the entry of decrees, judgments of condemnation were entered and the products were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

1695. Misbranding of Far-Vet Merco-Tabs No. 1, Udder Ointment, and Guaidine Tablets. U. S. v. 418 Bottles of Merco-Tabs No. 1, 71 Bottles of Udder Ointment, 285 Bottles of Guaidine Tablets, and a number of circulars. Consent decree of condemnation. Products ordered released under bond. (F. D. C. No. 16146. Sample Nos. 18566-H, 18567-H, 18570-H.)

LIBEL FILED: May 29, 1945, District of Minnesota.

ALLEGED SHIPMENT: The drugs were shipped between the approximate dates of December 1, 1943, and January 16, 1945, from Kansas City, Mo., by the George A. Lopp Laboratories.

PRODUCT: 418 100-tablet bottles of *Merco-Tabs No. 1*, 71 15-ounce bottles of *Udder Ointment*, and 285 100-tablet bottles of *Guaidine Tablets* at St. Paul,

Minn., together with a number of circulars entitled "Dealers' Price List 1944" and "Price List 1944," which accompanied the *Merco-Tabs No. 1*.

Examination disclosed that the *Merco-Tabs No. 1* consisted essentially of mercury bichloride, 2 grains per tablet, zinc sulfocarbolate, sodium citrate and carbonate, and green coloring matter; that the *Udder Ointment* consisted essentially of phenol, methyl salicylate, turpentine, eucalyptol, lanolin, and petrolatum, colored with D&C Red No. 17; and that the *Guaidine Tablets* consisted essentially of potassium dichromate, iodine, creosote, potassium guaiacolsulfonate, and salt.

LABEL, IN PART: "Far-Vet Merco-Tabs No. 1 Quart Size [or "Udder Ointment" or "Guaidine Tablets"] * * * Distributed by Farmers Veterinary Supply Co., St. Paul, Minn."

NATURE OF CHARGE: *Merco-Tabs No. 1*, misbranding, Section 502 (a), the label statements, "for drinking water medication * * * Directions Dissolve 1 tablet to one quart of drinking water. In aggravated cases, use 2 tablets to one quart of water. At the first sign of an outbreak begin treatment immediately, continuing for about a week and repeating twice a week thereafter as indicated," were false and misleading since they represented and suggested that the article would be of value in the prevention or treatment of diseases of poultry, whereas the article would not be of value for such purposes; and the statements in the circulars, "For fowl cholera, typhoid, coccidiosis, and blackhead in poultry. One tablet dissolved in a gallon of water will make the best intestinal disinfectant for poultry" and "For Fowl Cholera, Typhoid and Coccidiosis," were false and misleading since the article, when used as directed, would have no value in the treatment or prevention of fowl cholera, typhoid, coccidiosis, or blackhead in poultry, nor would it be effective as an intestinal disinfectant.

Udder Ointment, misbranding, Section 502 (a), the label statements, "Udder Ointment * * * For local application of non-tubercular inflammation of the udder of both cows and mares," were false and misleading since they represented and suggested that the article would be effective for the relief and treatment of inflammation of the udders of cows and mares, whereas the article would not be effective for such purposes.

Guaidine Tablets, misbranding, Section 502 (a), the label statements, "One tablet per gallon of drinking water. Allow no other water during treatment. Repeat as indicated," were false and misleading since they represented and suggested that the article, when used as directed, would be of value in the treatment of sick animals, whereas the article would be of no value for such purposes.

DISPOSITION: July 19, 1945. Joseph Pogoriler, trading as the Farmers Veterinary Supply Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

1696. Misbranding of "Stock-O" Stock and Poultry Medicine. U. S. v. 40 Packages and 102 Packages of "Stock-O" Stock and Poultry Medicine. Default decree of condemnation. Portion of product ordered destroyed; remainder ordered delivered to the National Zoological Park. (F. D. C. Nos. 16153, 16154. Sample Nos. 2735-H, 3219-H.)

LIBELS FILED: May 17 and 18, 1945, District of Maryland and District of Columbia.

ALLEGED SHIPMENT: On or about November 8, 1944, and April 6, 1945, from Charlottesville, Va., by the Stock-O Co., Inc.

PRODUCT: 40 packages of the above-named product at Washington, D. C., and 102 packages at Denton, Md.

Examination showed that the product contained sulfur, iron sulfate, epsom salt, mercury, camphor, and plant material, including asafoetida, pepper, and nux vomica.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article, when used as directed, would be effective in the treatment of bloody and other types of coccidiosis, colds, brooder pneumonia, cholera, fowl typhoid, roup, limberneck, a run-down condition, and other common diseases of poultry; and that it would be effective as a wormer, tonic, and builder. The article would not be effective for such purposes. Further misbranding, Section 502 (e) (2),

the label failed to bear the name and quantity or proportion of strychnine contained in the article.

Further misbranding, Section 502 (b), the statement, "Net Weight * * * 24 ounces," appearing on the label of the article in the Maryland lot, was false and misleading since the article contained considerably less than 24 ounces.

DISPOSITION: June 8 and September 5, 1945. No claimant having appeared, judgments of condemnation were entered and the product in the Maryland lot was ordered destroyed, and that in the District of Columbia lot was ordered delivered to the National Zoological Park, for use as poultry feed.

1697. Misbranding of Williams Horse, Cattle and Sheep Medicine and Williams Hog Medicine. U. S. v. 13 Sacks of Williams Horse, Cattle and Sheep Medicine and 4 Sacks of Williams Hog Medicine (and 2 other seizure actions against both products). Decrees of condemnation. Products ordered released under bond. (F. D. C. Nos. 16100 to 16102, incl. Sample Nos. 22556-H, 22557-H, 24352-H, 24353-H.)

LABELS FILED: On or about May 4 and 8, 1945, Eastern District of Arkansas, Western District of Louisiana, and Northern District of Mississippi.

ALLEGED SHIPMENT: Between the approximate dates of May 31, 1944, and February 23, 1945, by the Williams Stock Medicine Co., Inc., from Quincy, Ill. Two booklets entitled "Williams Horse, Cattle and Sheep Medicine" had been sent by the same shipper from Quincy, Ill., the exact dates being unknown.

PRODUCT: *Williams Horse, Cattle and Sheep Medicine*, 13 sacks at Tallulah, La., 36 sacks at Clarksdale, Miss., and 25 bags at Earle, Ark. *Williams Hog Medicine*, 4 sacks at Tallulah, La., and 5 bags at Earle, Ark. Two booklets entitled "Williams Horse, Cattle and Sheep Medicine" were located at Earle, Ark. There was also enclosed in the sacks a circular containing representations concerning another product of the shipper, "Williams Medicine."

Examination of a sample of the *Horse, Cattle and Sheep Medicine* disclosed that the product consisted essentially of 50 percent salt, 16 percent glauber salt, 3 percent soda, 3 percent calcium carbonate, charcoal, and plant material, including 0.014 percent of nicotine. Examination of a sample of the *Williams Hog Medicine* disclosed that the product consisted essentially of 58 percent glauber salt, 25 percent calcium carbonate, 5 percent soda, 1 percent salt, charcoal, and plant material, including 0.01 percent of nicotine.

NATURE OF CHARGE: *Williams Hog Medicine*, misbranding, Section 502 (a), the statement on the label, "The Hog Grower," and certain statements in a leaflet enclosed in the bag, were false and misleading since they represented and suggested that the article would be effective as a hog grower; that it would be effective to expel worms or condition hogs; that it would overcome run-down conditions in hogs; and that it would otherwise favorably influence the health and development of hogs. The article would not be efficacious for such purposes. Further misbranding (portions of both products), Section 502 (a), certain statements in the accompanying booklets entitled "Williams Horse, Cattle and Sheep Medicine" were false and misleading since they represented and suggested that the products would be effective to enable stock to grow faster, gain more quickly, and keep in better condition; that they would be effective to expel worms, rid hogs of worms, and prevent reinfestation by worms; that they would be effective to stop pigs from coughing and cattle from bloating; that they would prevent malnutrition in cows; that they would be effective to keep horses and mules fit; and that they would act as tonic conditioners, appetizers, and digestive regulators. The products would not be effective for such purposes. Further misbranding of *Williams Horse, Cattle and Sheep Medicine* under Section 502 (a) was alleged because of false and misleading claims in the labeling of the article that another product of the shipper, *Williams Hog Medicine*, would supply mineral elements lacking in the regular rations; that it would make strong, hefty, healthy hogs; that it would help get them to market in the shortest time; that the said *Williams Hog Medicine* was a vermifuge; and that another product of the firm, referred to as "Williams Medicine," would make stock thrive better or pay better profits. The other products referred to in the labeling of the *Williams Horse, Cattle and Sheep Medicine* would not be effective for the purposes recommended. Further misbranding (all lots), Section 502 (e) (2), they were fabricated from 2 or more ingredients and their labels failed to bear the common or usual name of each active ingredient.

DISPOSITION: Between May 17 and October 2, 1945. The Delta Grocery and Cotton Co., Clarksdale, Miss., having appeared as claimant for the Clarksdale lot, and the Williams Stock Medicine Co., Inc., having appeared as claimant for the remaining lots, judgments of condemnation were entered and the products were ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF DECEPTIVE PACKAGING

1698. Misbranding of Sealtext. U. S. v. 16 Dozen Packages of Sealtext. Default decree of destruction. (F. D. C. No. 15309. Sample No. 18927-H.)

LIBEL FILED: March 5, 1945, District of Minnesota.

ALLEGED SHIPMENT: On or about December 6, 1944, and January 2, 1945, by the Sealtext Co., from Chicago, Ill.

PRODUCT: 16 dozen packages of *Sealtext* at Minneapolis, Minn. The product consisted of a roll of gauze with a paper wrapper, enclosed in a carton. The diameter of the roll of gauze with its paper wrapping was 1½ inches. The carton, the depth of which was approximately that of the length of the roll, had a cross section 2 by 2 inches.

NATURE OF CHARGE: Misbranding, Section 502 (i) (1), the container of the article was so made and filled as to be misleading since the carton was materially larger than was necessary to hold the roll of bandage contained therein.

DISPOSITION: April 26, 1945. No claimant having appeared, judgment was entered ordering that the product be delivered to charitable institutions or destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ACCURATE STATEMENTS OF THE QUANTITY OF THE CONTENTS*

1699. Misbranding of isopropyl rubbing compound. U. S. v. 40 Dozen Bottles of Isopropyl Rubbing Compound. Default decree of condemnation and destruction. (F. D. C. No. 16094. Sample No. 2273-H.)

LIBEL FILED: May 18, 1945, Eastern District of North Carolina.

ALLEGED SHIPMENT: On or about August 26 and October 13, 1943, by the Adde Co., from Baltimore, Md.

PRODUCT: 40 dozen bottles of *isopropyl rubbing compound* at Kinston, N. C. Examination showed that the product was short-volume.

LABEL, IN PART: "Mild Isopropyl Rubbing Compound * * * 6 Fluid Ounces."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the label of the article failed to bear an accurate statement of the quantity of contents.

DISPOSITION: July 16, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1700. Misbranding of ammonium alum and aromatic spirits of ammonia. U. S. v. 11 Dozen Packages of Ammonium Alum and 17 Dozen Packages of Aromatic Spirits of Ammonia. Default decree of condemnation. Products ordered delivered to a charitable institution. (F. D. C. No. 15443. Sample Nos. 23713-H, 23714-H.)

LIBEL FILED: On or about March 1, 1945, Southern District of Texas.

ALLEGED SHIPMENT: On or about January 29, 1945, by McKesson and Robbins, Inc., from Memphis, Tenn.

PRODUCT: 11 dozen packages of *ammonium alum* and 17 dozen packages of *aromatic spirits of ammonia* at Houston, Tex.

LABEL, IN PART: "Four Ounces Alum Lump Ammonium Alum * * * Packaged by Van Vleet Laboratories," and "½ Fluid Oz. Aromatic Spirit of Ammonia * * * Manufactured by Van Vleet Laboratories."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the *ammonium alum* was short of the declared weight, and the *aromatic spirits of ammonia* was short of the declared volume.

DISPOSITION: April 18, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered delivered to a charitable institution.

*See also Nos. 1656, 1696.

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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS—Continued

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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1701-1750**DRUGS AND DEVICES**

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., September 6, 1946.

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**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

1701. Misbranding of sulfathiazole tablets. U. S. v. Abraham H. Kaitz (American Proprietaries). Plea of guilty. Fine, \$500. Sentence of 3 months in jail suspended and defendant placed on probation for 6 months. (F. D. C. No. 16571. Sample No. 4701-H.)

INFORMATION FILED: November 8, 1945, Eastern District of Pennsylvania, against Abraham H. Kaitz, trading as American Proprietaries, at Philadelphia, Pa.

INTERSTATE SHIPMENT: On or about June 17, 1944, from New York, N. Y., to Philadelphia, Pa., of a quantity of *sulfathiazole tablets*.

LABEL, WHEN SHIPPED: "1000 Tablets Sulfathiazole U. S. P. XII 0.5 Gram (7.7 grains) Ominis Orbis Warner * * * Caution: To be used only by or on the prescription of a physician * * * William R. Warner & Co., Inc. New York St. Louis."

NATURE OF CHARGE: That on or about January 12, 1945, the defendant removed a number of tablets from a bottle bearing the label described above, repacked the tablets into a box bearing the label, "Sal-T Directions one 4 times a day No. 2 TR-TAB TTK," and sold those tablets without a prescription.

The information charged further that the act of the defendant resulted in the misbranding of the article in the following respects: Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since

*For failure to bear adequate directions or warning statements, see No. 1701; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 1719, 1746, 1747; omission of, or unsatisfactory, ingredients statements, Nos. 1720, 1736, 1746; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 1742, 1743; cosmetics, subject to the drug provisions of the Act, Nos. 1741, 1742.

the directions, "one 4 times a day," borne on the labeling, were not adequate directions for use; and, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: December 4, 1945. A plea of guilty having been entered, the court imposed a fine of \$500 and sentenced the defendant to serve 3 months in jail. The jail sentence was suspended and the defendant was placed on probation for 6 months.

1702. Adulteration and misbranding of boric acid ointment. U. S. v. S. Pfeiffer Manufacturing Co. and John A. Mueller. Pleas of nolo contendere. Corporate defendant fined \$200; individual defendant fined \$20. (F. D. C. No. 16593. Sample Nos. 5625-H, 5626-H.)

INFORMATION FILED: November 13, 1945, Eastern District of Missouri, against the S. Pfeiffer Manufacturing Co., a corporation, St. Louis, Mo., and John A. Mueller, plant manager for the corporation.

ALLEGED SHIPMENT: On or about October 7, 1944, from the State of Missouri into the State of Connecticut.

PRODUCT: Examination of samples disclosed that the product did not contain any boric acid, but that it contained, in the two samples examined, 0.3 percent and 0.58 percent, respectively, of oil of mustard.

LABEL, IN PART: "Gold Medal * * * Boric Acid Ointment U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (d), a substance containing oil of mustard had been substituted in whole or in part for "Boric Acid Ointment U. S. P."

Misbranding, Section 502 (a), the label statements, "Boric Acid Ointment U. S. P." and "A soothing emollient ointment for Chafing, Bruises, Sunburn, Minor Burns and Scalds, and Minor Skin Irritations * * * Cleanse affected area well and apply ointment once or twice daily. Cover with clean gauze or bandage if possible," were false and misleading since the article was not "Boric Acid Ointment U. S. P.," and it was not a soothing emollient ointment for the conditions stated.

Further misbranding, Section 502 (j), the article, because of the presence of oil of mustard, was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, "cleanse affected area well and apply ointment once or twice daily. Cover with clean gauze or bandage if possible."

DISPOSITION: January 15, 1946. Pleas of nolo contendere having been entered on behalf of the defendants, the court imposed upon the corporate defendant a fine of \$100 on each of 2 counts; and the court also imposed upon the individual defendant a fine of \$10 on each of 2 counts.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1703. Misbranding of Hyatrone Androgenic Hormone Preparation. U. S. v. 20 Jars of Hyatrone Androgenic Hormone Preparation, and an accompanying booklet. Default decree of condemnation and destruction. (F. D. C. No. 19013. Sample No. 7323-H.)

LIBEL FILED: January 28, 1946, District of New Jersey.

ALLEGED SHIPMENT: From New York, N. Y., by the Johay Corporation. The product was shipped on or about August 4, 1945, and the booklet was shipped subsequent to that date.

PRODUCT: 20 jars of *Hyatrone Androgenic Hormone Preparation* at Hohokus, N. J., together with a booklet entitled "Hyatrone * * * Hormone Preparations for Men and Women."

LABEL, IN PART: "Hyatrone Androgenic Hormone Preparation Contains 36,100 MG Pure Crystalline Testosterone."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article, in the booklet, and in a letter addressed to the consignee by the Johay Corporation, were false and misleading since they represented and suggested that the article would combat old age, compensate hormone deficiency, prolong the prime of life, restore the vigor of youth, build new tissues, promote endurance, improve mental capacity, stimulate new strength, correct impotency, and renew confidence. The labeling represented further that the article would

abolish the troublesome symptoms associated with the male climacteric occurring during middle age; that it would be efficacious in the treatment of emotional instability, despondency, irritability, fatigability, insomnia, diminution of mental powers, hearing, and potency, and, in severe cases, flushes and sweats; and that it would be useful in cases of benign prostatic hypertrophy, for the relief of pain in certain forms of heart disease, such as angina pectoris, and for the improvement of peripheral circulation in certain arterial diseases, such as arteriosclerosis. The labeling also represented that use of the article would result in a clearer brain, better hearing, a stronger voice, improved resistance of the nervous system against fatigue, promotion of muscular development, strength, and endurance, and increased potency. The article would not be effective to fulfill the promises of benefit stated and implied.

Violation of Section 505, the article was a new drug which should not have been introduced into interstate commerce since it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, "Massage into skin $\frac{1}{2}$ level teaspoon of Hyatrone until completely absorbed. Repeat this treatment each morning and night for six consecutive days. Stop treatment for five days. Resume treatment for six days. Discontinue for fourteen days and begin cycle anew until results are satisfactory. Thereafter only $\frac{1}{2}$ level teaspoon is required as a maintenance dose in the above cycle"; and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: February 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1704. Adulteration of Comfort's Spiced Bitters. U. S. v. Aschenbach & Miller, Inc., and Laurence W. Helweg. Plea of nolo contendere. Corporation fined \$500; imposition of sentence upon the individual defendant was suspended, and he was placed on probation for 30 days. (F. D. C. No. 16606. Sample No. 3427-H.)

INFORMATION FILED: November 29, 1945, Eastern District of Pennsylvania, against Aschenbach & Miller, Inc., Philadelphia, Pa., and Laurence W. Helweg, secretary and treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 18, 1945, from the State of Pennsylvania into the State of Virginia.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of rodent hair fragments and insect fragments; and, Section 501 (a) (2), it had been prepared under insanitary conditions whereby it may have become contaminated with filth.

DISPOSITION: March 25, 1946. Pleas of nolo contendere having been entered, the court imposed a fine of \$500 against the corporation. The court suspended imposition of sentence upon the individual defendant and placed him on probation for 30 days.

1705. Adulteration of buchu leaves. U. S. v. 3 Bales of Buchu Leaves. Default decree of condemnation and destruction. (F. D. C. No. 19100. Sample No. 35613-H.)

LABEL FILED: February 12, 1946, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about December 6, 1945, by R. J. Prentiss and Co., from New York, N. Y.

PRODUCT: 3 bales, each containing 280 pounds, of *buchu leaves* at St. Louis, Mo.

LABEL, IN PART: "E. M. & Co. Produce of Union of South Africa Buchu Leaves With Stems."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects and insect fragments.

DISPOSITION: March 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1706. Adulteration of flaxseed. U. S. v. 14 Barrels of Flax Seed. Default decree of condemnation and destruction. (F. D. C. No. 19101. Sample No. 35616-H.)

LIBEL FILED: February 12, 1946, Eastern District of Missouri; amended libel filed on or about March 5, 1946.

ALLEGED SHIPMENT: On or about October 13, 1945, by the Bisbee Linseed Co., from Chicago Heights, Ill.

PRODUCT: 14 barrels, each containing 250 pounds, of *flaxseed* at St. Louis, Mo.

LABEL, IN PART: "Pure Cleaned Flax Seed Kellogg & Miller Inc. Amsterdam, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects.

DISPOSITION: March 21, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF THE PRESENCE OF NONCERTIFIED COAL-TAR COLORS

1707. Adulteration of elixir phenobarbital. U. S. v. 95 Jugs of Elixir Phenobarbital. Default decree of condemnation and destruction. (F. D. C. No. 18635. Sample No. 5141-H.)

LIBEL FILED: December 7, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 15, 1945, by the Standard-Drug Co., Inc., from Newark, N. J.

PRODUCT: 95 1-gallon jugs of *elixir phenobarbital* at Philadelphia, Pa.

LABEL, IN PART: "Elixir Phenobarbital Green * * * For use as a sedative and hypnotic."

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained a coal-tar dye, Ext. D&C Blue #1, which is certified for use only in externally applied drugs and cosmetics.

DISPOSITION: January 10, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1708. Adulteration of phenobarbital tablets. U. S. v. 1 Package of Phenobarbital Tablets. Decree of condemnation and destruction. (F. D. C. No. 19212. Sample No. 12265-H.)

LIBEL FILED: February 18, 1946, District of Maine.

ALLEGED SHIPMENT: On or about September 18, 1945, by Moore & Co., Inc., from Worcester, Mass.

PRODUCT: 1 package containing approximately 98,000 *phenobarbital tablets* at Springvale, Maine. Examination of a sample disclosed that the product was colored with "methyl violet 4 RN," a coal-tar color which is not one that, according to regulations, may be certified as suitable for use in drugs.

LABEL, IN PART: "Compressed Tablets Purple Each Tablet Contains Phenobarbital 1/2 Gr."

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article bore and contained, for purposes of coloring only, a coal-tar color that has not been listed for use in drugs in accordance with regulations and is other than one from a batch that has been certified.

DISPOSITION: March 8, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1709. Adulteration of redistilled water, and misbranding of posterior pituitary injection. Two indictments: U. S. v. E. S. Miller Laboratories, Inc. Pleas of nolo contendere. Fine of \$500 on each indictment. (F. D. C. Nos. 16539, 16588. Sample Nos. 62266-F, 27436-H.)

INDICTMENTS RETURNED: October 3, 1945, Southern District of California, against the E. S. Miller Laboratories, Inc., Los Angeles, Calif.

*See also Nos. 1702, 1703.

ALLEGED SHIPMENT: On or about November 13 and December 26, 1944, from the State of California into the States of Texas and Oregon.

NATURE OF CHARGE: *Redistilled water*, adulteration, Section 501 (b), the quality and purity of the article fell below the standard for *redistilled water* set forth in the National Formulary, an official compendium. The standard provides that *redistilled water* shall meet the requirements for clearness of ampul solutions set forth in the compendium, and that it shall meet the requirements of the pyrogen test set forth in the United States Pharmacopoeia. The article did not meet the requirements for clearness of ampul solutions since it was not clear but contained undissolved material, and it did not meet the requirements of the pyrogen test set forth in the United States Pharmacopoeia; and the difference in quality and purity of the article from the standard was not stated on its label.

Posterior pituitary injection, misbranding, Section 502 (a), the label statements, "Posterior Pituitary Injection * * * 20 U. S. P. Units per cc" and "Posterior Pituitary U. S. P. * * * each cubic centimeter contains 20 International Units," were false and misleading since they represented and suggested that each cubic centimeter of the article possessed a physiological activity equivalent to 20 U. S. P. posterior pituitary units. The article possessed a physiological activity of not more than 1.2 U. S. P. posterior pituitary units per cubic centimeter.

DISPOSITION: December 18, 1945. Pleas of *nolo contendere* having been entered on behalf of the defendant, the court imposed a fine of \$500 on each indictment.

1710. Adulteration of triple distilled water. U. S. v. 224 Packages of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 17626. Sample No. 3655-H.)

LIBEL FILED: October 2, 1945, District of Maryland.

ALLEGED SHIPMENT: On or about August 9, 1945, from Brooklyn, N. Y., by E. Tosse and Co.

PRODUCT: 224 packages, each containing 10 ampuls, of *triple distilled water* at Baltimore, Md.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be both "Ampuls of Redistilled Water," the name of which is recognized in the National Formulary, and "Water for Injection," the name of which is recognized in the United States Pharmacopoeia, official compendiums, but its quality and purity fell below the standard set forth therein since it was contaminated with undissolved material.

DISPOSITION: November 7, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1711. Adulteration and misbranding of calcium gluconate. U. S. v. 11 Boxes of Calcium Gluconate. Default decree of condemnation. Product ordered delivered to the Federal Security Agency. (F. D. C. No. 18690. Sample No. 7678-H.)

LIBEL FILED: December 20, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about November 1, 1945, by the S. E. Massengill Co., from Bristol, Tenn.

PRODUCT: 11 boxes, each containing 25 ampuls, of *calcium gluconate* at New York, N. Y. Examination of a sample showed that the product contained, in addition to calcium gluconate, 0.9 percent of boric acid.

NATURE OF CHARGE: Adulteration, Section 501 (d), boric acid had been substituted in part for *calcium gluconate*.

Misbranding, Section 502 (a), the label designation, "Ampuls Calcium Gluconate," was misleading as applied to the article, which differed in the identity of its contained ingredients from that defined and described in the United States Pharmacopoeia under the title "Calcium Gluconate Ampuls."

DISPOSITION: February 6, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered for the use of the Federal Security Agency.

1712. Adulteration of dextrose in lactate—Ringer's solution. U. S. v. 14 Cases of Dextrose in Lactate—Ringer's Solution. Consent decree of condemnation and destruction. (F. D. C. No. 18003. Sample No. 30774-H.)

LIBEL FILED: October 19, 1945, District of Colorado.

ALLEGED SHIPMENT: On or about September 19, 1945, by the Cutter Laboratories, from Oakland, Calif.

PRODUCT: 14 cases, each containing 6 500-cc. bottles, of *dextrose in lactate—Ringer's solution*.

LABEL, IN PART: "Saftiflask Dextrose 5% W/V in Lactate—Ringer's Solution."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it purported to be for intravenous use and it contained undissolved material, whereas an article which purports to be for intravenous use should be free from undissolved material.

DISPOSITION: November 5, 1945. The Cutter Laboratories having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1713. Adulteration and misbranding of estrogenic substance. U. S. v. 12 Bottles of Estrogenic Substance. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 16187. Sample No. 22140-H.)

LIBEL FILED: May 19, 1945, Southern District of Illinois.

ALLEGED SHIPMENT: On or about December 7, 1944, by the Intramed Co., Inc., from New York, N. Y.

PRODUCT: 12 bottles of *estrogenic substance* at Decatur, Ill.

Examination disclosed that the potency of the product was substantially less than the 50,000 International Units of estrone per cubic centimeter, which it was represented to have.

LABEL, IN PART: (Bottle) "1000 cc. Estrogenic Substance * * * 50,000 I. U./cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement, "Estrogenic Substance * * * 50,000 I. U./cc," was false and misleading.

DISPOSITION: March 19, 1946. The Intramed Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1714. Adulteration of sodium iodide ampuls. U. S. v. 21 Cartons of Sodium Iodide. Default decree of condemnation and destruction. (F. D. C. No. 17937. Sample Nos. 29944-H, 29945-H, 29947-H, 29948-H.)

LIBEL FILED: October 19, 1945, Northern District of California.

ALLEGED SHIPMENT: Between the approximate dates of April 9, 1943, and March 24, 1945, from Bristol, Tenn.-Va., by the S. E. Massengill Co.

PRODUCT: 7 cartons, each containing 6 ampuls, and 14 cartons, each containing 25 ampuls, of *sodium iodide* at San Francisco, Calif.

LABEL, IN PART: "10 cc [or "20 cc"] Size Sodium Iodide * * * in Distilled Water Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: November 21, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1715. Adulteration of sodium thiosulfate. U. S. v. 31 Boxes of Sodium Thiosulfate. Consent decree of condemnation and destruction. (F. D. C. No. 15722. Sample Nos. 6391-H to 6393-H, incl.)

LIBEL FILED: March 23, 1945, Southern District of New York.

ALLEGED SHIPMENT: From Indianapolis, Ind.

PRODUCT: 31 boxes, each containing 6 ampuls, of *sodium thiosulfate* at New York, N. Y.

Examination showed that the product, when seized at New York, N. Y., was contaminated with particles of sulfur resulting from the disintegration of the *sodium thiosulfate*, the disintegration probably having occurred after the completion of the manufacturing processes.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Thiosulfate," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was not free from undissolved material.

DISPOSITION: On November 7, 1945, Eli Lilly and Co. of Indianapolis, Ind., and New York, N. Y., having appeared as claimant, an agreement was entered into between the claimant and the Government. It contained the following provisions:

"FIRST: At and subsequent to the time of their seizure by the United States Marshal said ampoules of Sodium Thiosulfate contained and now contain, in small quantity, minute particles of undissolved sulphur.

"SECOND: Upon completion of their manufacture, said ampoules of Sodium Thiosulfate were inspected by Claimant and were found by it to be free of undissolved material, and the presence in said ampoules of Sodium Thiosulfate of particles of undissolved sulphur is accounted for by the fact that such sulphur may have precipitated out of solution subsequent to completion by the Claimant of the manufacturing, inspection and packaging thereof. In the case of Sodium Thiosulfate, sulphur not infrequently precipitates out of solution after the same has been properly compounded and prepared.

"THIRD: The allegations of the libel herein are true in that by reason of the presence of the aforesaid minute particles of undissolved sulphur in said ampoules of Sodium Thiosulphate the same are not free from undissolved material.

"AND IT IS FURTHER STIPULATED, CONSENTED AND AGREED that a decree may be entered herein which shall recite the foregoing facts and condemn said ampoules of Sodium Thiosulfate."

On November 14, 1945, judgment of condemnation was entered, reciting the provisions of the above-mentioned agreement and containing a finding by the court that the product was adulterated in that it contained minute particles of undissolved sulfur as described in the agreement. On November 28, 1945, an amended decree was entered, ordering that the product be destroyed.

1716. Adulteration and misbranding of oil of cassia. U. S. v. 1 Can of Oil of Cassia. Default decree of condemnation and destruction. (F. D. C. No. 17181. Sample No. 14776-H.)

LIBEL FILED: September 11, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 30, 1945, by Standard Synthetics, Inc., from New York, N. Y.

PRODUCT: 1 10-pound can of *oil of cassia* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a volatile oil other than "Oil of Cassia U. S. P." had been substituted in whole or in part for the article.

Misbranding, Section 502 (a), the label statement, "Oil of Cassia Redistilled U.S.P.," was false and misleading as applied to the article.

DISPOSITION: January 18, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1717. Adulteration and misbranding of rhubarb. U. S. v. 1 Bag of Rhubarb. Default decree of condemnation and destruction. (F. D. C. No. 18980. Sample No. 43242-H.)

LIBEL FILED: January 14, 1946, District of Maryland.

ALLEGED SHIPMENT: On or about October 4, 1945, by R. J. Prentiss and Co., Inc., from New York, N. Y.

PRODUCT: 1 bag containing 97 pounds of *rhubarb* at Baltimore, Md. This product consisted of a mixture of about $\frac{1}{3}$ rhapontic rhubarb and $\frac{2}{3}$ Indian rhubarb, with a small proportion of a hybrid of these two varieties. The official product consists of varieties of rhubarb grown in China and Tibet. It does not include rhapontic rhubarb.

LABEL, IN PART: "Rhubarb USP Except For Origin"; (invoiced) "Whole Rhubarb Root USP."

NATURE OF CHARGE: Adulteration, Section 501 (d), a substance other than the official product had been substituted for "Rhubarb U.S.P."

Misbranding, Section 502 (a), the label statement, "Rhubarb USP Except for Origin," was false and misleading as applied to the article, which had an identity different from that of rhubarb defined in the United States Pharmacopoeia.

DISPOSITION: February 19, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1718. Adulteration and misbranding of Blood Tonic, Expectorant, Asthmatic Solution, and Antirheumatic Ampuls. U. S. v. William John Chittick (Chittick Biochemic Laboratories). Plea of nolo contendere. Fine, \$250 and costs. (F. D. C. No. 16531. Sample Nos. 96256-F, 96257-F, 18922-H, 18923-H.)

INFORMATION FILED: November 27, 1945, Eastern District of Illinois, against William John Chittick, trading as the Chittick Biochemic Laboratories, at Paris, Ill.

ALLEGED SHIPMENT: On or about August 17, 1944, and January 16, 1945, from the State of Illinois into the States of Indiana and Wisconsin.

PRODUCT: Analyses disclosed that the *Blood Tonic* consisted chiefly of water, glycerin, gualacol, myrrh, and calcium hydroxide, but that it contained no iron, potassium, or magnesium phosphates; that the *Expectorant* consisted of a clear red liquid containing, chiefly, water and glycerol, with minute amounts of creosote, sodium, and calcium, and unidentified red color, but that it contained no sodium iodide, no hexamethylenamine, and only a trace of calcium; that the *Asthmatic Solution* was a colorless liquid containing 0.099 gram of methenamine per 10 cc., and iodides and phosphates of sodium and calcium; and that the *Antirheumatic Ampuls* contained 5.0 grains of sodium iodide and 9.3 grains of sodium salicylate per 10 cc. The products also contained considerable quantities of insoluble material.

NATURE OF CHARGE: *Blood Tonic*, adulteration, Section 501 (c), the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since it was represented to contain 1 grain of iron phosphate, 1 grain of potassium phosphate, 1 grain of magnesium phosphate, and 10 grains of calcium per 10 cc., and it was represented to be of a purity and quality appropriate and suitable for intravenous use, whereas it contained no iron phosphate, no potassium phosphate, no magnesium phosphate, and only a trace of calcium, and it would not be appropriate and suitable for intravenous use because of contamination with undissolved material. Misbranding, Section 502 (a), the label statements, "Each 10 C C Ampoule contains * * * Iron Phosphate 1 grain, Potassium Phosphate 1 grain, Magnesium Phosphate 1 grain, Calcium 10 grains," were false and misleading; and the label statements, "Blood Tonic * * * Indicated in Anemia and all diseases where the blood is below normal. Increases the Haemoglobin percent and the red cell count," were false and misleading since they represented and suggested that the article, when administered as directed, would be efficacious in increasing the hemoglobin percent and the red cell count of the blood; and that it would be efficacious in the cure, mitigation, treatment, and prevention of anemia and all diseases in which the blood is below normal. The article would not be efficacious for such purposes.

Expectorant, adulteration, Section 501 (c), the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since it was represented to contain 5 grains of sodium iodide, 5 grains of calcium, and 3 grains of hexamethylenamine per 10 cc., and it was represented to be of a purity and quality appropriate and suitable for intravenous use, whereas it contained no sodium iodide, no hexamethylenamine, and only a trace of calcium, and it would not be appropriate and suitable for intravenous use because of contamination with undissolved material. Misbranding, Section 502 (a), the label statements, "Each 10 cc ampoule contains * * * Sodium Iodide, 5 grs., Calcium 5 grs., Hexamethylenamine 3 grs.," were false and misleading; and the label statements, "Expectorant and Alterative * * * General Debility, Tuberculosis, Pneumonia and Diseases of the Respiratory Tract," were false and misleading since they represented and suggested that the article, when used as directed, would be efficacious as an expectorant and alterative; and that it would be efficacious in the cure, mitiga-

tion, treatment, and prevention of general debility, tuberculosis, pneumonia, and diseases of the respiratory tract. The article would not be efficacious for such purposes.

Asthmatic Solution, adulteration, Section 501 (c), the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since it was represented to be of a purity and quality appropriate and suitable for intravenous use, whereas it was not appropriate and suitable for such use because of contamination with undissolved material. Misbranding, Section 502 (a), the label statement "Asthmatic Solution" was false and misleading since it represented and suggested that the article, when used as directed, would be efficacious in the cure, treatment, and prevention of asthma. The article would not be efficacious for such purpose.

Antirheumatic Ampuls, adulteration, Section 501 (c), the strength of the article differed from and its purity and quality fell below that which it purported and was represented to possess, since it was represented to contain 15 grains of sodium iodide and 15 grains of sodium salicylate per 10 cc., and it was represented to be of a purity and quality appropriate and suitable for intravenous use, whereas it contained less than 15 grains of sodium iodide and less than 15 grains of sodium salicylate per 10 cc., and it was not appropriate and suitable for intravenous use because of contamination with undissolved material. Misbranding, Section 502 (a), the label statements, "Each 10 cc Ampoule contains Sodium Iodide 15 grains, Sodium Salicylate 15 grains," were false and misleading; and the label statements, "Antirheumatic * * * Indications—Rheumatism, Influenza, Streptic sore throat, Chronic Arthritis," were false and misleading since they represented and suggested that the article, when used as directed, would be efficacious in the cure, mitigation, treatment, and prevention of rheumatism, influenza, streptic sore throat, and chronic arthritis. The article would not be efficacious for such purposes.

DISPOSITION: December 21, 1945. A plea of nolo contendere having been entered, the court imposed a fine of \$250 and costs.

1719. Adulteration and misbranding of L. G. Rubbing Compound. U. S. v. 15 Cases of Rubbing Compound. Default decree of forfeiture. Product ordered delivered to a charitable institution. (F. D. C. No. 18028. Sample No. 25561-H.)

LIBEL FILED: October 23, 1945, District of Idaho.

ALLEGED SHIPMENT: On or about February 7, 1945, by the Lura-Glo Laboratories, from Oakland, Calif.

PRODUCT: 15 cases, each case containing 24 bottles, of *rubbing compound* at Twin Falls, Idaho. Analysis showed that the product contained approximately 30 percent by volume of isopropyl alcohol. It was labeled as containing 70 percent of isopropyl alcohol. All bottles of the product contained less than 1 pint, the volume declared.

LABEL, IN PART: "L. G. Rubbing Compound Isopropyl."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement, "Isopropyl Alcohol 70% by Volume," was false and misleading; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: December 14, 1945. No claimant having appeared, judgment of forfeiture was entered and the product was ordered delivered to a charitable institution.

1720. Adulteration and misbranding of Pratt's Poultry Worm Powder and misbranding of Pratt's N-K Capsules. U. S. v. 68 Packages of Pratt's N-K Capsules and 9 Packages of Pratt's Poultry Worm Powder. Default decree of condemnation and destruction. (F. D. C. No. 18396. Sample Nos. 3921-H, 3923-H.)

LIBEL FILED: November 19, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about October 13, 1944, and August 17 and September 14, 1945, by the Pratt Food Co., from Philadelphia, Pa.

PRODUCT: 68 packages each containing 100 *Pratt's N-K Capsules*, and 6 8-ounce packages and 3 2½-pound packages of *Pratt's Poultry Worm Powder* at Flemington, N. J.

Analysis revealed that the *Pratt's N-K Capsules* each consisted essentially of nicotine, 2.35 percent, phenothiazine, 2.88 percent, and a small amount of strychnine; and that the *Pratt's Poultry Worm Powder* consisted essentially of nicotine, 4 percent, phenothiazine, 7.66 percent in the 8-ounce package and 8.98 percent in the 2½-pound package, and small amounts of copper sulfate and strychnine.

NATURE OF CHARGE: *Pratt's Poultry Worm Powder*, adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it was represented to contain 12 percent of phenothiazine, but contained less than that amount. Misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be effective for the removal of all species of worms which infest poultry, and that it would be effective against cecal worms in poultry, whereas it would not be effective for such purposes; and the label statement, "Active Ingredients * * * Phenothiazine 12.00 percent" was false and misleading.

Pratt's N-K Capsules, misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article would have some special action in releasing the different ingredients at different times in the intestinal tract, for the elimination of the different species of worms that infest poultry, and that the article would be effective in the treatment of cecal worms (*Heterakis gallinae*) and capillaria species of worms that infest the intestinal tract of poultry. The article did not possess the special action stated and implied, and it would not be effective in the treatment of the conditions mentioned. Further misbranding, Section 502 (a), the label statement, "Improved Formula Phenothiazine Added," was misleading in that it suggested that phenothiazine was present in the product in sufficient amounts to be effective as an active ingredient for the removal of cecal worms which infest chickens and turkeys, whereas phenothiazine was not present in the product in sufficient amounts to be effective as an active ingredient for such purposes; and, Section 502 (a) (2), the label of the article did not bear the common or usual name of each active ingredient.

DISPOSITION: February 5, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1721. Adulteration and misbranding of Watkins Veterinary Salve. U. S. v. 29½ Dozen Packages of Watkins Veterinary Salve. Default decree of destruction. (F. D. C. No. 18322. Sample No. 21176-H.)

LIBEL FILED: On or about November 6, 1945, Western District of Missouri.

ALLEGED SHIPMENT: On or about October 4, 1945, by the J. R. Watkins Co., from Winona, Minn.

PRODUCT: 29½ dozen packages, each containing 11 ounces, of *Watkins Veterinary Salve* at Kansas City, Mo. Examination showed that the product was a brown, aromatic semi-solid containing not more than 0.35 percent of chloramine-T.

LABEL, IN PART: "Watkins Veterinary Salve Active Ingredients * * * Chloramine T . . . 3.10%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since the article failed to contain 3.10 percent of chloramine-T.

Misbranding, Section 502 (a), the label statement, "Chloramine T . . . 3.10%," was false and misleading; and the label statements, "Watkins Veterinary Salve promotes the healing of superficial wounds, certain burns and cuts for it contains an ingredient which deters the growth of bacteria," were false and misleading as applied to the article, which contained no ingredient capable of producing the results stated and implied by those statements.

DISPOSITION: December 5, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1722. Adulteration and misbranding of adhesive strips. U. S. v. 118 Cartons of Adhesive Strips. Default decree of condemnation and destruction. (F. D. C. No. 19173. Sample No. 16062-H.)

LIBEL FILED: February 13, 1946, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about December 19, 1945, by the Hampton Manufacturing Co., from Carlstadt, N. J.

PRODUCT: 118 cartons, each containing 12 packages, of *adhesive strips* at Detroit, Mich.

LABEL, IN PART: "12 Blue Cross—Sterilized Adhesive Strips Sulfathiazole pad."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement, "Sterilized Adhesive Strips," was false and misleading; and, Section 502 (i) (1), the container of the article was so made, formed, and filled as to be misleading since the adhesive strips occupied only approximately 46 percent of the capacity of the package.

DISPOSITION: May 13, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1723. Misbranding of Diet Supplement No. 4B. U. S. v. Dr. Pierre A. Boncquet (Dr. P. A. Boncquet Products). Plea of not guilty. Verdict of guilty. Fine, \$300. Sentence of 1 year in jail suspended; defendant placed on probation for 3 years. (F. D. C. No. 14277. Sample No. 62752-F.)

INFORMATION FILED: March 10, 1945, Southern District of California, against Dr. Pierre A. Boncquet, trading as Dr. P. A. Boncquet Products, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about March 25, 1944, from the State of California into the State of Missouri.

PRODUCT: Examination of the product indicated that it was an aqueous, syrupy suspension containing large amounts of reducing sugars and smaller amounts of dissolved and undissolved proteinaceous matter, lactic acid, calcium, iron, chloride, phosphate, and a trace of manganese.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "A Reconstruction Diet with Vital Raw Organs from Healthy Animals" were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of cardiac deficiency, high blood pressure, low blood pressure, juvenile raches, uremia, stomach ulcers, diarrhea, constipation, spasticity, neuritis, arteriosclerosis, arthritis, steatorrhea, biliousness, acne pimples, heart deficiency, stomach deficiency, anemia, kidney and liver deficiency, headache, and neuralgia. The article would not be efficacious for such purposes.

The article, together with another product, *Diet Supplement No. 10*, was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On May 22, 1945, the defendant having entered a plea of not guilty, the case came on for trial before a jury. This trial resulted in a jury disagreement. Thereafter, the case was retried before another jury, resulting in a verdict of guilty; and on October 16, 1945, the court imposed a fine of \$150 on each of counts 1 and 2 relating to the *Diet Supplement No. 4B* and a sentence of 1 year in jail with respect to count 3 relating to the *Diet Supplement No. 10*. The jail sentence was suspended and the defendant was placed on probation for 3 years.

*See also Nos. 1702, 1709, 1711, 1713, 1716-1722.

1724. Misbranding of Paracelsus. U. S. v. American Biochemical Corporation. Plea of guilty. Fine, \$600. (F. D. C. No. 14281. Sample Nos. 3786-F, 3787-F, 59316-F.)

INFORMATION FILED: May 16, 1945, Northern District of Ohio, against the American Biochemical Corporation, Cleveland, Ohio.

ALLEGED SHIPMENT: From the State of Ohio into the States of Missouri and Illinois. The product was shipped on or about November 26 and 29 and December 16, 1943, and was accompanied by a number of circulars which were shipped between October 30, 1943, and January 5, 1944.

PRODUCT: Analysis disclosed that the product contained calcium lactate, sodium phosphate, magnesium sulfate, potassium iodide, manganese carbonate, iron aluminate, potassium chloride, sodium chloride, sodium bicarbonate, sodium sulfate, lithium carbonate, and organic matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars which accompanied the article, and which were entitled "Paracelsus Food and Health," "The Active Life of These Two is the Wonder of Their Friends," and "Here's What They Say About Paracelsus," were false and misleading since they represented and suggested that the article was a body builder and tonic, by reason of its mineral content; that it would be effective in the cure, mitigation, treatment, and prevention of arthritis, rheumatism, neuritis, coughs, asthma, and general debility; that it would be of value in improving the functions of all body organs; and that it would provide vigor and vitality, aid digestion, and purify the blood. The article would not be efficacious for the purposes represented or accomplish the results claimed.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 26, 1945. A plea of guilty having been entered, the court imposed a fine of \$100 on each of 6 counts.

1725. Misbranding of Kaldak. U. S. v. 19 Cans and 22 Cans of Kaldak. Default decree of condemnation and destruction. (F. D. C. No. 18707. Sample No. 29580-H.)

DISPOSITION. November 26, 1945. A plea of guilty having been entered, the

ALLEGED SHIPMENT: On or about October 12, 1945, by the Kaldak Co., from Lansing, Mich.

PRODUCT: 19 12-ounce cans and 22 5-ounce cans of *Kaldak* at San Francisco, Calif. The product was represented on its label as containing dried brewer's yeast, irradiated yeast, reduced iron, and dicalcium phosphate. Examination indicated that it had essentially the composition declared on its label.

LABEL, IN PART: "Kaldak A Dietary Food Supplement Providing Natural Vitamin B Complex, Vitamin D, Iron, Calcium and Phosphorus."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular headed "Faulty body chemistry may often contribute to symptoms of," in a leaflet headed "Proof Aplenty about Kaldak," and in a display placard headed "try Kaldak," which were shipped with the article, were false and misleading since they represented and suggested that the article would be effective in the treatment and prevention of a wide variety of diseases, conditions, and symptoms, including arthritis, neuritis, colitis, constipation, anemia, digestive disorders, chronic fatigue, high blood pressure, thyroid trouble, sinus trouble, low blood pressure, kidney trouble, and nervousness. The article would not be effective in the treatment and prevention of the diseases, conditions, and symptoms stated and implied.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 19, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1726. Misbranding of Bush Cal-O-Stace, Bush's All-In-One Broth, and Bush Kelp Tablets. U. S. v. 660 Cartons of Bush Cal-O-Stace, 260 Cartons of Bush's All-In-One Broth, 12 Cartons of Bush Kelp, and approximately 150 books. Default decree of condemnation and destruction. (F. D. C. No. 18061. Sample Nos. 2942-H to 2944-H, incl.)

LIBEL FILED: October 26, 1945, District of Columbia.

PRODUCT: 660 cartons, each containing 250 tablets, of *Bush Cal-O-Stace*; 260 cartons, each containing 12 ounces, of *Bush's All-In-One Broth*; and 12 car-

tons, each containing 200 tablets, of *Bush Kelp*, which products were held for sale in the District of Columbia by David V. Bush, together with approximately 150 accompanying books entitled "What To Eat."

LABEL, IN PART: (*Cal-O-Stace*) "Each tablet contains: Dicalcium Phosphate, Calcium Carbonate and Malt Diastase * * * Six tablets per day supplies 65% of the adult minimum daily requirement for Calcium, and 19% of this requirement for Phosphorus"; (*All-In-One-Broth*) "Ingredients: Bush All-In-One Broth Carrot Powder; White Celery Powder; Whole Barley; Onion Powder; Pimiento Powder; Tomato Powder; Salt; Orange Powder; Irish Moss Powder; Okra Powder; Alfalfa Dust; Chili Powder; Watercress Parsley Powder; Celery Seed; Garlic Powder; Vegetable Protein; Sodium Glutamate Derivative"; (*Bush Kelp*) "Bush Kelp Tablets, compressed into tablet form for your convenience, are pure, carefully dehydrated Pacific Ocean Kelp, or marine vegetation."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying books were false and misleading since they represented and suggested that the articles, singly or in combination, would be effective for the reduction of weight, for internal cleansing, for body building, and for taking down the waistline to normal; that they would be effective in preventing many serious conditions of a chronic nature which are due to a deficiency of calcium and phosphorus in the body; that they would be effective for nourishing skin, teeth, bones, lung tissue, nerves, fingernails, and toenails; that they would be effective to give strength and vitality to resist disease; that they would be effective to repair the bodies of adults and children and to overcome run-down conditions resulting from improper food intake; and that they would supply an important proportion of the body's need for phosphorus. The articles, singly or in combination, would not be effective for those purposes.

They were also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 14, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1727. Misbranding of Pa-Po-Ya. U. S. v. 109 Bottles of Pa-Po-Ya. Default decree of condemnation. Product ordered delivered for the use of St. Elizabeth's Hospital. (F. D. C. No. 18017. Sample No. 2940-H.)

LABEL FILED: October 18, 1945, District of Columbia.

PRODUCT: 57 1-pint bottles, 44 1-quart bottles, and 8 1-gallon bottles of *Pa-Po-Ya*, held for sale in the District of Columbia in the possession of the Citrus Juice Co., Washington, D. C. Examination showed that the product was a syrup with a burning taste, and that it possessed no protein digestive properties.

LABEL, IN PART: "Pa-Po-Ya * * * A concentrate syrup (Tropical Laboratory Process) made from the Tropical Melon, Papaya, including skin, pulp and seed; sugars, inverted with fruit acid—added, honey, fruit and vegetable flavors * * * The Tropical Tree-Melon Papaya. So rich in Natural Vitamins A-B-C-G and ten minerals plus a natural aid to digestion (Pa-pain)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label were false and misleading since they represented and suggested that the article would be effective for aiding digestion, giving health, curing, and vitalizing; that it would be effective in treating stomach disorders, sore throat, and eczema; that it would be effective in combating acidosis; that it would be effective for indigestion, gastric disorders, disorders of children, and many other ailments; that it possessed the power of digesting protein; and that it would aid in avoiding "morning after disaster." The article would not be effective for such purposes.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 28, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a Government institution in the District of Columbia.

1728. Misbranding of Kol-N-Zyme. U. S. v. 14 Packages of Kol-N-Zyme and 117 leaflets. Default decree of condemnation and destruction. (F. D. C. No. 18321. Sample No. 14423-H.)

LABEL FILED: On or about November 2, 1945, Northern District of Ohio.

ALLEGED SHIPMENT: From Chicago, Ill., by the Beacon Products Co. The product was shipped on or about August 13, 1945, and the leaflets were shipped on or about April 19, 1945.

PRODUCT: 14 packages of *Kol-N-Zyme* and 117 leaflets entitled "*Kol-N-Zyme*," at Orrville, Ohio. Examination showed that the product consisted essentially of karaya gum, ground psyllium seed, and other plant products, together with sugars.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the leaflets were false and misleading since the article, which was essentially a bulk-forming laxative, would not be effective to fulfill the promises of benefit stated and implied: "Health conscious people have seldom been offered a product that presents a combination of aids for Better Living, well being and return to normal digestive function, than the combined ingredients in balanced proportion contained in *Kol-N-Zyme*. * * * Laxatives containing irritants achieve no healing result or correction of the cause of costiveness, or failure of normal evacuation. * * * Coating agents such as bismuth, okra, and other palliatives, likewise fail to correct the cause of tenderness, or irritation in the stomach, intestines or colon. * * * The ingredients contained in *Kol-N-Zyme* are formulated in balance, and are recognized for their value in aiding the return of normal functioning of elimination as outlined in the following paragraphs. * * * Mucus, effete and necrotic matter, inactivated tissues are proteins which may be digested by the Papay Enzyme, thus converting a foul condition to a clean condition which is the first principal of healing therapy. * * * Fruit Pectin is well known for its value as a healing agent when ulcer or irritation is present."

DISPOSITION: December 7, 1945. No claimant having appeared, judgment of condemnation was entered and the product and leaflets were ordered destroyed.

1729. Misbranding of Yogurt Culture. U. S. v. 9 Cartons of Yogurt Culture, and enclosed circulars. Default decree of condemnation and destruction. (F. D. C. No. 18262. Sample No. 23350-H.)

LABEL FILED: On or about November 9, 1945, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about September 27, 1945, by the Health Food Jobbers, from Chicago, Ill.

PRODUCT: 9 cartons, each containing 1 bottle, of *Yogurt Culture* at St. Louis, Mo., together with enclosed circulars entitled "*Yogurt Culture A Health Aid*." Examination indicated that the product was a culture of viable lactobacilli, as represented in its labeling.

LABEL, IN PART: "Rosell Institute's Original Yogurt Culture * * * International Yogurt Company, Los Angeles, California."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that consumption of milk cultured with the article would enable the user to enjoy better than average health, to retain beauty for a long time, and to keep the spirit of youth for many years; that it would greatly aid health and vitality, prolong life, prevent dysfunction of the vital organs, particularly the gastrointestinal tract, prevent premature old age, and fight unfriendly microbes; and that it constituted an adequate treatment for chronic constipation, colitis, ulcers, and allied intestinal conditions. The article would not be effective for such purposes.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 29, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1730. Misbranding of Tolergen Tablets. U. S. v. 50 Packages of Tolergen Tablets, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 15071. Sample No. 92865-F.)

LABEL FILED: January 18, 1945, District of Columbia.

PRODUCT: 50 packages of *Tolergen Tablets* which were offered for sale by the Vita Health Food Co., at Washington, D. C. The product was accompanied by a number of leaflets entitled "The Riddle of Allergy," and each package of the product contained a circular entitled "Are you Allergic."

Examination of a sample indicated that the product possessed approximately the composition declared upon its label.

LABEL, IN PART: "Tolergen * * * each tablet contains: Ascorbic Acid . . . (100 Mg.) 2000 U. S. P. Units, Irradiated Ergosterol . . . 150 U. S. P. Units, Dicalcium Phosphate Anhydrous 5 grains * * * Distributors Research Drug Company, Inc. 100 Fifth Avenue New York."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in the circulars and leaflets were false and misleading since they represented and suggested that the article would be effective in the prevention and relief of allergic distress, hay fever, rose fever, asthma, eye catarrh, migraine, bad breath, nausea, skin rashes, eczema, hives, diarrhea, itch, pimples, and indigestion; and that it would promote the general health and strength. The article would not be effective for such purposes.

DISPOSITION: October 3, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1731. Misbranding of Tolergen Tablets. U. S. v. 10 Bottles and 18 Bottles of Tolergen Tablets. Default decree of condemnation and destruction. (F. D. C. No. 18680. Sample No. 29579-H.)

LIBEL FILED: January 4, 1946, Northern District of California.

ALLEGED SHIPMENT: On or about October 5, 1945, by the Western Natural Foods Co., from Seattle, Wash.

PRODUCT: 10 40-tablet bottles and 18 50-tablet bottles of *Tolergen Tablets* at Berkeley, Calif.

LABEL, IN PART: "Tolergen * * * Each tablet contains: Ascorbic Acid (100 mg.)—2000 U. S. P. Units Irradiated Ergosterol (supplying Vitamin D—150 U. S. P. Units) Dicalcium Phosphate Anhydrous—5 grains with excipient * * * Distributors Research Drug Company, Inc. 100 Fifth Avenue—New York."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars shipped with the article and entitled, "The Riddle of Allergy Now Medical Science has the Answer" and "What to do about your Cosmetic Allergy," were false and misleading since they represented and suggested that the article would be effective for the relief of allergic conditions such as hay fever, rose fever, asthma, eye catarrh, migraine, bad breath, nausea, skin rashes, eczema, hives, diarrhea, itch, pimples, and indigestion; and that it would be effective in the treatment of skin affections, nose and throat troubles, and digestive disturbances. The labeling represented and suggested further that the article would fortify the system against the causes of allergic distress; that it would be beneficial in improving the general condition; and that it would be effective in establishing systemic resistance to allergies. It also represented and suggested that the article would be effective to correct cosmetic allergies and skin troubles caused by wearing apparel; that it would build up a resistance to allergy-producing substances, so that any favorite cosmetic could be used without fear of annoying and unsightly skin troubles; that irritation, roughness, chapping, dryness, and unsightly eruptions of the skin caused by the use of cosmetics would be corrected; and that use of the article would result in clear, glowing, and entirely fresh looking skin. The article would not be effective for the purposes represented.

DISPOSITION: March 19, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1732. Misbranding of Lock's Oil Eucalyptus Compound. U. S. v. 518 Bottles of Lock's Oil Eucalyptus Compound. Default decree of condemnation and destruction. (F. D. C. No. 18145. Sample No. 2951-H.)

LIBEL FILED: November 15, 1945, District of Columbia.

PRODUCT: 125 1-ounce bottles, 125 2-ounce bottles, 260 4-ounce bottles, and 8 8-ounce bottles of *Lock's Oil Eucalyptus Compound*, held and intended for sale in the District of Columbia in the possession of the G. C. Murphy Co., Washington, D. C. The product was accompanied by labeling consisting of a

streamer bearing the words "Why Suffer With a Cold Locks Medicines," and framed printed matter headed "Eucalyptus, A Distillate of the fresh leaves" and "Cold, Common."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling accompanying the product were false and misleading since they represented and suggested that it would be effective for colds, fermentative dyspepsia, intestinal parasites, and other affections of the alimentary tract, for infections of the air passages, as in common cold or influenza, and for remedying conditions resulting in foul sputum; and that, when mixed with olive oil, it would be effective in the treatment of rheumatism. The article would not be effective for such purposes.

DISPOSITION: January 7, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1733. Misbranding of Laken's 9 Drops Capsules and Liquid. U. S. v. 20 Boxes of Laken's 9 Drops Capsules, 33 Combination Packages of Laken's 9 Drops Capsules and Liquid, and 1 display card. Default decree of condemnation and destruction. (F. D. C. No. 18204. Sample Nos. 4864-H, 4865-H.)

LABEL FILED: On or about October 31, 1945, District of New Jersey.

ALLEGED SHIPMENT: From Philadelphia, Pa. The products were shipped by David H. Blank & Co. on or about August 29 and September 27, 1945, and the placard was shipped on or about August 29, 1945, by Harry Laken, owner of the Marshall Drug Co., Philadelphia, Pa., and manufacturer of the product.

PRODUCT: 20 boxes of *Laken's 9 Drops Capsules* and 33 combination packages of *Laken's 9 Drops Capsules and Liquid* at Camden, N. J., together with 1 display card entitled "Why Suffer with Rheumatic Pains, Get that New Discovery Laken's 9 Drops To-Day." A circular entitled "Laken's 9 Drops What It is" was enclosed in some of the packages of the products, and a circular entitled "Facts Everyone Should Know About" was enclosed in other packages.

Examination disclosed that the capsules consisted essentially of $3\frac{1}{2}$ grains of aspirin, 2.6 grains of acetophenetidin, and 1 grain of caffeine citrate per capsule; and that the liquid consisted essentially of sodium salicylate, potassium iodide, water, and a trace of an alkaloid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars and on the display card, and the design of a man in pain appearing in the circular entitled "Facts Everyone Should Know About," were false and misleading since they represented and suggested that the articles, alone or in combination, would be effective in the treatment of rheumatism, lumbago, arthritis, stiff and swollen joints, backache, and neuritis; that they would be effective as an analgesic and uric acid solvent; that they would be effective to get at the main cause of so-called rheumatism; that they would be effective in the treatment of the suffering and discomfort associated with common colds and in the treatment of sciatica; and that they would be effective to activate the kidneys and eliminate uric acid poison. The articles, alone or in combination, would not be effective for those purposes.

DISPOSITION: March 1, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1734. Misbranding of Laken's 9 Drops Capsules and Liquid. U. S. v. 22 Combination Packages of Laken's 9 Drops Capsules and Liquid (and 1 seizure action against another lot of the same products). Default decrees of condemnation and destruction. (F. D. C. Nos. 18417, 18430. Sample Nos. 4771-H, 4888-H.)

LABELS FILED: On or about November 27 and December 4, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about September 5 and October 26, 1945, by the Marshall Drug Co., from Philadelphia, Pa.

PRODUCT: 22 combination packages of *Laken's 9 Drops Capsules and Liquid* at Paulsboro, N. J.; and 21 combination packages of the same products, together with 6 packages of *Laken's 9 Drops Capsules*, at Camden, N. J.

Examination showed that the capsules consisted essentially of aspirin, acetophenetidin, and caffeine; and that the liquid consisted essentially of sodium salicylate, potassium iodide, water, and a trace of an alkaloid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and the design of a man in pain appearing in the circular entitled "Facts Everyone Should Know About," enclosed in the combination packages of the articles, were false and misleading since they represented and suggested that the articles would be effective in the treatment of rheumatism, arthritis, backache, swollen joints, lumbago, neuritis, rheumatic pains, and stiff joints; that they would be effective as an analgesic to get at the main cause of so-called rheumatism; and that they would be effective in the treatment of the suffering and discomfort associated with common colds. The articles would not be effective for those purposes.

DISPOSITION: March 1, 1946. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1735. Misbranding of Laken's 9 Drops Capsules and Liquid. U. S. v. 32 Packages of Laken's 9 Drops Capsules and Liquid. Default decree of condemnation and destruction. (F. D. C. No. 18632. Sample No. 4889-H.)

LABEL FILED: On or about December 11, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about October 29, 1945, by Smith, Kline and French, Inc., from Philadelphia, Pa.

PRODUCT: 32 packages of *Laken's 9 Drops Capsules and Liquid* at Haddon Heights, N. J. The composition of these products was identical with, and they were misbranded in the same respect as, the products reported in the preceding notice of judgment, No. 1734.

DISPOSITION: March 1, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1736. Misbranding of Frencos's Pap-Tabs, Papaya Tooth Powder, and Papain Powdered Absolute. U. S. v. 127 Cartons of Frencos's Pap-Tabs, 285 Cartons of Frencos's Papaya Tooth Powder, and 23 Cartons of Frencos's Papain Powdered Absolute. Default decrees of condemnation and destruction. (F. D. C. Nos. 17653, 17654. Sample Nos. 29949-H to 29951-H, incl.)

LIBELS FILED: October 15 and 17, 1945, Northern District of California.

ALLEGED SHIPMENT: Between the approximate dates of March 23 and August 13, 1945, by the Frencos Laboratories, from Nogales, Ariz.

PRODUCT: 127 cartons of *Frencos's Pap-Tabs* and 285 cartons of *Frencos's Papaya Tooth Powder* at Oakland, Calif.; and 23 cartons of *Frencos's Papain Powdered Absolute* at San Francisco, Calif.

Analyses disclosed that the *Pap-Tabs* consisted essentially of bismuth, calcium, and magnesium compounds, including carbonates, papain, and starch; that the *tooth powder* consisted essentially of sodium, calcium, and magnesium carbonates and chlorides, papain, starch, and soap; and that the *Papain Powdered Absolute* consisted essentially of papain.

NATURE OF CHARGE: *Pap-Tabs*, misbranding, Section 502 (a), the label statement, "Contains * * * Calcium, Magnesium, Kaolin, Bismuth," was false and misleading since the article contained no kaolin, and it did not contain calcium, magnesium, and bismuth as such but contained compounds of those minerals. In addition, certain statements in the circulars entitled "Frencos Laboratories of Nogales" and "Frencos Pap-Tabs," which were shipped with the article, were false and misleading since they represented and suggested that the article would be effective as a digestant; and that it would be effective in the treatment of digestive disorders, sea-, air-, car-, and train-sickness, and alcoholism. The article would not be effective for such purposes. Further misbranding, Section 502 (e) (2), the article failed to bear the common or usual name of each active ingredient.

Tooth powder, misbranding, Section 502 (a), certain statements on the carton and in the circular entitled "Frencos Laboratories of Nogales" were false and misleading since they represented and suggested that the article would be effective in digesting foreign materials present in the mouth; and that it would be effective in the treatment of pyorrhea and sore gums. The article would not be effective for such purposes.

Papain Powdered Absolute, misbranding, Section 502 (a), the following statements on the carton containing the article were false and misleading since papain is not capable of accomplishing the results stated and implied, and it is not a rich source of protein and vitamins: "Papain is a food that

digests food. It is high in protein. Papaya is strong in Vitamin A as well as B, C and D. It also has recently been discovered to contain some G * * * Frencos Powdered Papain is an excellent specific in most cases of gastric distress, and also indicated in general dyspeptic ailments. * * * Added to milk for those who have difficulty in digesting, will give excellent results. * * * It is sometimes used in face creams as a * * * blemish remover * * * tonic."

DISPOSITION: November 21, 1945. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1737. Misbranding of Min-E-Vita. U. S. v. 11 Cartons of Min-E-Vita and a number of leaflets, booklets, and display cards. Default decree of condemnation and destruction. (F. D. C. No. 18241. Sample No. 25115-H.)

LIBEL FILED: On or about November 9, 1945, Northern District of Texas.

ALLEGED SHIPMENT: On or about May 21, 1945, by Helios Foods, Inc., from Chicago, Ill.

PRODUCT: 11 cartons of *Min-E-Vita*, 11 leaflets entitled "Why Min-E-Vita?" and 111 booklets and 35 display cards entitled "Min-E-Vita versus Gray Hair," at Dallas, Tex.

LABEL, IN PART: "Min-E-Vita * * * 30 Mineral Tablets * * * Calcium Phosphorus Iron—Sodium Potassium Aluminum Copper—Iodine Magnesium Manganese * * * 30 Vitamin Capsules * * * Each Capsule Contains Not Less Than: Vitamin A—5000 U. S. P. Units Vitamin B₁—333 U. S. P. Units Vitamin C—600 U. S. P. Units Vitamin D—500 U. S. P. Units Vitamin B₂—G—1,000 Gammas-Riboflavin Vitamin E—2 Minims Wheat Germ Oil Plus 10 Milligrams Calcium Pantothenate Anti-Gray Hair Vitamin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the accompanying leaflets, booklets, and display cards were false and misleading since they represented and suggested that the article would be effective to restore the original color to gray hair, to insure health and vitality, to build resistance to disease, and to provide essential minerals not readily and easily available from common foods; and that it would be effective in the treatment and prevention of low resistance, frequent colds, hay fever, asthma, pimples, acne, eczema, hyperacidity, acidosis, arthritic conditions, general debility, painful, difficult menstruation, insomnia, nervous disorders, waning sexual vigor, listlessness, fatigue, and digestive and heart disorders. The article would not be effective for those purposes.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: December 20, 1945. No claimant having appeared, judgment of condemnation was entered and the product, together with the printed matter, was ordered destroyed.

1738. Misbranding of Kia-Spa Mineral Bath. Kia-Fem Modern Feminine Hygiene, and Kia-Oro Mouth Wash. U. S. v. 20 Bottles of Kia-Spa Mineral Bath, 1 Bottle of Kia-Fem Modern Feminine Hygiene, and 7 Bottles of Kia-Oro Mouth Wash. Default decree of condemnation and destruction. (F. D. C. No. 18165. Sample Nos. 32246-H, 32248-H, 32249-H.)

LIBEL FILED: November 13, 1945, District of Arizona.

ALLEGED SHIPMENT: On or about April 2 and July 3, 1945, by the Kia-Min Laboratories, from Los Angeles, Calif.

PRODUCT: 13 32-ounce bottles and 7 64-ounce bottles of *Kia-Spa Mineral Bath*, 1 8-ounce bottle of *Kia-Fem Modern Feminine Hygiene*, and 7 8-ounce bottles of *Kia-Oro Mouth Wash* at Glendale, Ariz., together with a number of circulars entitled "Man's Rightful Heritage."

Analyses disclosed that all products consisted of water and an iron compound, very small proportions of calcium, aluminum, and magnesium compounds, with traces of phosphates and iodides.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the labels of the articles, "Contains The Following Ingredients: Sulphate Chloride Sodium Phosphoric Acid Iron Silica Alumina Iodine Magnesium Manganese Potassium Calcium," were misleading since they failed to reveal the material fact that the articles did not contain a significant proportion of any

ingredient except iron sulfate; and, Section 502 (e), the labels of the articles failed to bear the common or usual names of their active ingredients.

Further misbranding, Section 502 (a). The statement on the label of the *Kia-Spa Mineral Bath*, "Recommended as aid in the elimination of Toxic Body Wastes through activation of the pores," was false and misleading since the article, when placed in the bath water, would not be effective to eliminate toxic body wastes. The statements on the label of the *Kia-Fem Modern Feminine Hygiene*, "Healing * * * Recommended as an aid in the elimination of Leucorrhea and other offensive discharges," were false and misleading since the article would not be healing, and it would not aid in the elimination of leucorrhea and other offensive discharges. The statements on the label of the *Kia-Oro Mouth Wash*, "Recommended as an aid in correcting unhealthy conditions of the mouth and gums. * * * For severe conditions use more frequently," were false and misleading since the article would not be effective as an aid in correcting unhealthy conditions of the mouth and gums.

DISPOSITION: January 18, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1739. Misbranding of B-I-F Combination. U. S. v. 40 Cartons of B-I-F Combination. Default decree of condemnation and destruction. (F. D. C. No. 18349. Sample No. 2374-H.)

LIBEL FILED: November 9, 1945, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about September 19, 1945, by W. C. Hughes and Co., Inc., from Baltimore, Md.

PRODUCT: 40 cartons of *B-I-F Combination*, each carton containing 1 bottle of *B-I-F Emulsion* and 1 bottle of *B-I-F Injection*, at Norfolk, Va.

Examination disclosed that the *Emulsion* consisted essentially of balsam of copaiba, oil of cassia, sugar, glycerin, water, a gum, and a potassium compound; and that the *Injection* consisted essentially of zinc acetate, glycerin, a small proportion of carbolic acid, and water, colored with caramel.

LABEL, IN PART: (Leaflet enclosed in carton) "*B-I-F Combination An Emulsion (For Internal Use) An Injection (With Syringe) Directions Shake the bottle containing the Injection which is red, fill the syringe full, and inject the contents slowly into the urinal passage, holding the syringe in the right hand. Allow the medicine to remain 20 to 30 seconds. The Emulsion, which is white, should be taken internally three times a day, before meals, in teaspoonful doses, in the morning on arising, at noon and at bedtime. The injection should be used about the same time, and always after passing water.*"

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading since it represented and created the impression that the article, when taken as directed, would be effective in the treatment of gonorrhea. The article would not be effective for that purpose.

DISPOSITION: January 30, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1740. Misbranding of Gyro-Lator. U. S. v. a number of devices known as Gyro-Lator, and a number of circulars. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 18157. Sample No. 31369-H.)

LIBEL FILED: October 19, 1945, Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of June 11 and August 10, 1945, from Chicago, Ill., by the Gyro-Lator Division of the Aciform Corporation.

PRODUCT: A number of devices consisting of 1 *Unit A*, 22 *Unit B*, and 3 *Unit C Gyro-Lators* at Los Angeles, Calif., together with 700 circulars entitled "Directions For the Use of Gyro-Lator Units," 500 circulars entitled "Gyroducting Method," 200 circulars entitled "The Gyro-Lator," and 500 circulars entitled "A 'Weigh' With All Flesh."

The letters A, B, and C were used to distinguish different sizes of the device. Each device contained an electric motor connected to it in such a manner that it would produce a vibration or oscillation.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the device would be effective to bring about a reduction in weight; and that it would be effective in the treatment of vasoconstriction, stasis, nerve and

muscular fatigue, pain, inflammation, atrophy, tetany, edema, congestion, constipation, colds, bronchitis, asthma, painful backs, posture, myelitis, neuritis, neuromuscular disturbance of back and shoulders, kidney disorders, flatulence, lumbago, chest pain, lung congestion, pleuritis, sacro-iliac conditions, spinal disorders, sciatica; ovarian, prostatic, bladder, rectal, and menstrual disorders; varicose veins, phlebitis, fractures, cardiac disturbances, arthritis, colitis, liver conditions, indigestion, blood pressure, bursitis, metatarsal troubles, bunions, sinus and respiratory disorders, headache, irregular heart, joint disturbances, angina pectoris, aneurysm, bone disease, bowel obstruction, chilblains, colic; diseases of the duodenum, pancreas, ovaries, rectum, spine, spinal cord, stomach, and uterus; fallen arches, flatfoot, gastro-enteritis, gastric ulcer, gallbladder trouble, gallstones, gout, hysteria, influenza, laryngitis, locomotor ataxia, lung congestion, meningitis, mumps, neuralgia, neurasthenia, peritonitis, pelvic inflammation, pharyngitis, pleurisy, pneumonia, rheumatism, enlarged spleen, tonsillitis, varicocele, writer's cramp, menopausal disorders, impeded venous circulation, and muscle spasm. The article would not be effective for such purposes.

DISPOSITION: November 28, 1945. The Aciform Corporation, Chicago, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond, conditioned that the literature be destroyed and the product relabeled under the supervision of the Federal Security Agency.

1741. Misbranding of Dr. Page-Barker's British Hair Lotion. U. S. v. 51 Dozen Packages of Hair Lotion and 75 display cards. Default decree of destruction. (F. D. C. No. 18265. Sample No. 29097-H.)

LABEL FILED: November 8, 1945, Northern District of California.

ALLEGED SHIPMENT: From Seattle, Wash., by Page-Barker Distributors of America. The lotion was shipped between the approximate dates of August 27 and October 3, 1945, and the display cards were shipped on or about September 20, 1945.

PRODUCT: 51 dozen packages of *hair lotion* in counter display cartons, at San Francisco, Calif., also 75 display cards reading, in part, "Guaranteed to Clear up Dandruff," "A Challenge to the Millions of Americans Troubled by Dandruff," and "Beautiful Hair begins with a Healthy Scalp."

Examination showed that the product consisted essentially of water, sulfur, salicylic acid, and boric acid or borate, together with yellow coloring matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and on the display cards were false and misleading since they represented and suggested that the article would be effective in the treatment and eradication of dandruff; that it would be effective in treating the causes of scalp itching and irritation and scalp disorders in general; and that it would be effective to bring about a healthy scalp. The article would not be effective for such purposes.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: December 7, 1945. No claimant having appeared, judgment was entered ordering that the product be destroyed.

1742. Misbranding of Dio-Dane Scalp Cream. U. S. v. 32 Packages and 120 Packages of Dio-Dane Scalp Cream. Default decree of condemnation and destruction. (F. D. C. No. 18609. Sample Nos. 4347-H, 4348-H.)

LABEL FILED: November 28, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about May 14 and June 14, 1945, by Bonat & Bonat, Inc., from New York, N. Y.

PRODUCT: 32 1-pound packages and 120 2-ounce packages of *Dio-Dane Scalp Cream* at Trenton, N. J. Examination disclosed that the product consisted essentially of oil of cedar leaf, soap, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements, "for the improvement of scalp conditions. Recommended most highly for Dandruff * * * Falling Hair," were false and misleading since the article would not be effective in the improvement of all scalp conditions, and it would not be effective in the treatment of dandruff and falling hair.

Further misbranding, Section 502 (b) (1), the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor.
DISPOSITION: February 5, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1743. Misbranding of adhesive strips. U. S. v. 130 Packages of Adhesive Strips. Decree of condemnation and destruction. (F. D. C. No. 18987. Sample No. 11095-H.)

LIBEL FILED: January 18, 1946, District of Maine.

ALLEGED SHIPMENT: On or about February 1 and March 20, 1945, by the Young Novelty Co., Inc., from Boston, Mass.

PRODUCT: 130 packages, each containing 36 envelopes, of adhesive strips at Portland, Maine. Examination disclosed that the product possessed practically no adhesive property.

LABEL, IN PART: (Envelope) "Home-aid Brand 8 Adhesive Strips Distributed by Home-aid Sales Co. Boston, Massachusetts."

NATURE OF CHARGE: Misbranding, Section 502 (a), the designation "Adhesive Strips," borne on the label, was false and misleading as applied to the article, which possessed no significant adhesive property.

DISPOSITION: February 21, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE*

1744. Misbranding of Quickway K-N-O-X and Quickway Health-Tabs. U. S. v. 13 Bottles of Quickway K-N-O-X and 13 Jars of Quickway Health-Tabs. Tried to the court. Decree of condemnation and destruction. (F. D. C. No. 17342. Sample Nos. 16560-H, 16561-H.)

LIBEL FILED: On or about September 14, 1945, Eastern District of Illinois.

ALLEGED SHIPMENT: On or about April 26 and June 5, 1945, from Francesville, Ind., by the Quickway Products Co.

PRODUCT: 4 1-gallon bottles, 7 1-quart bottles, and 2 1-pint bottles of *Quickway K-N-O-X*, and 12 200-tablet jars and 1 1,000-tablet jar of *Quickway Health-Tabs* at Milford, Ill.

Examination disclosed that the *Quickway K-N-O-X* was a purple liquid consisting chiefly of an aqueous solution of epsom salt, with small proportions of potassium permanganate, dichromate, nitrate, and chlorate; and that the *Quickway Health-Tabs* were dark gray compressed tablets consisting of sodium chloride and very small proportions of potassium dichromate, guaiacol, and creosote, with not more than 0.9 milligram of combined iodine per tablet.

NATURE OF CHARGE: *Quickway K-N-O-X*, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be effective in the treatment or prevention of cholera, typhoid, pullorum, and other serious disease conditions of hens; that it would be effective in the treatment or prevention of diarrhea and other bowel disorders of baby chicks; that it would be effective to increase egg production; and that it was an antiseptic for drinking water. The article would not be effective for those purposes, and, when used as directed, it was not an antiseptic for drinking water.

Quickway Health-Tabs, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article would be effective in the treatment or prevention of colds, roup, and most respiratory diseases in fowls; that it would be effective in the treatment and prevention of brooder pneumonia, colds, chilling, and most forms of coccidiosis in baby chicks; and that it was an antiseptic for drinking water for baby chicks. The article would not be effective in the treatment or prevention in fowls and baby chicks of the disease conditions stated and implied, and it was not an antiseptic for drinking water for baby chicks when used as directed.

DISPOSITION: January 25, 1946. The Quickway Products Co., claimant, having filed an answer in the case, the matter came on for trial before the court. At the conclusion of the testimony, the court found that the products were

* See also Nos. 1720, 1721.

misbranded as alleged in the libel and entered a decree condemning the products and ordering their destruction.

1745. Misbranding of Dia-Tabs, Old Reliable Powder, and Ready-to-Use Inhalant Spray. U. S. v. 223 Boxes of Dia-Tabs, 60 Packages of Old Reliable Powder, and 25 Cans of Ready-to-Use Inhalant Spray. Default decrees of condemnation and destruction. (F. D. C. No. 18175. Sample Nos. 22176-H, 23466-H, 35110-H, 35111-H.)

LABELS FILED: October 17, 1945, Eastern District of Missouri.

ALLEGED SHIPMENT: Between the approximate dates of May 2 and September 5, 1945, from Cleveland, Ohio, by the G. E. Conkey Co.

PRODUCT: 223 boxes of *Dia-Tabs*, 60 packages of *Old Reliable Powder*, and 25 cans of *Ready-to-Use Inhalant Spray* at St. Louis, Mo.

Analyses disclosed that the *Dia-Tabs* contained 43 percent of boric acid, 1.55 percent of a manganese compound, 1.49 percent of an iron compound, small amounts of a reducing sugar, copper sulfate, and zinc, sodium, and calcium phenolsulfonates; that the *Old Reliable Powder* consisted essentially of 73 percent of a copper compound, 1.57 percent of a manganese compound, and small amounts of iron and aluminum compounds; and that the *Inhalant Spray* consisted essentially of 87 percent of mineral oil, with small amounts of pine oil, creosote, and camphor.

NATURE OF CHARGE: *Dia-Tabs*, misbranding, Section 502 (a). The label statement, "Inert Ingredients: * * * Boracic Acid 20%," was misleading as applied to a tablet consisting essentially of 43 percent of boric acid. Certain other label statements were false and misleading since they represented and suggested that the article, when used as directed, would be effective as an intestinal astringent for poultry; and that it would be effective in the treatment of extreme cases of diseases of poultry. The article, when used as directed, would not be effective as an intestinal astringent for poultry, and it would not be effective in the treatment of any disease condition of poultry.

Old Reliable Powder, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article, when used as directed, would be effective in the relief of congestion in the early stages of disease conditions of poultry; and that it would be effective in expelling mucus in the upper respiratory tract of birds. The article would not be effective for such purposes.

Inhalant Spray, misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the article, when used as directed, alone or in conjunction with the internal use of *Conkey's Old Reliable Powder*, would be effective in combating colds in poultry; and that it would be effective as a soothing aid for the mucous membrane of the upper respiratory tract of poultry. The article would not be effective for such purposes.

DISPOSITION: November 21, 1945. No claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

1746. Misbranding of Save'M. U. S. v. 3 Bottles of Save'M. Default decree of condemnation and destruction. (F. D. C. No. 18230. Sample No. 138-H.)

LABEL FILED: October 27, 1945, Southern District of Florida.

ALLEGED SHIPMENT: On or about September 22, 1945, by Emmett J. Smith & Daughter, from Nashville, Tenn.

PRODUCT: 3 bottles, each containing 1 gallon, of *Save'M* at St. Petersburg, Fla. Analysis disclosed that the product contained approximately 99½ percent of water and a small amount of an extract of plant material.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "Save'M for intestinal ailments in chickens and turkeys," created the false and misleading impression that the article would save chickens and turkeys from intestinal ailments; and that it would be effective in the prevention and treatment of intestinal ailments of chickens and turkeys.

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents, since no statements of quantity of contents appeared on the label; and, Section 502 (e) (2), the label failed to bear the common or usual name of the active ingredients of the article.

DISPOSITION: November 26, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1747. Misbranding of Floxspray, Poultry Inhalant. U. S. v. 13 Bottles of Floxspray, Poultry Inhalant. Default decree of condemnation and destruction. (F. D. C. No. 19213. Sample No. 4624-H.)

LIBEL FILED: February 13, 1946, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 14, 1946, by the Fox Co., from Newfield, N. J.

PRODUCT: 3 1-gallon bottles and 10 1-quart bottles of *Floxspray, Poultry Inhalant* at Doylestown, Pa. Examination of a sample showed that the product consisted essentially of mineral oil, with some pine oil, eucalyptus oil, and camphor. The label of the product did not bear a declaration of the quantity of the contents.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain label statements were false and misleading since they represented and suggested that the product would be effective in the treatment and prevention of colds in baby chicks and mature poultry, whereas the article would not be effective for those purposes; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: March 14, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1748. Misbranding of condensed buttermilk emulsion. U. S. v. 8 Pails, 2 Barrels, and 11 Kegs of Condensed Buttermilk Emulsion, and 3 circulars. Default decree of condemnation and destruction. (F. D. C. No. 18327. Sample No. 19294-H.)

LIBEL FILED: November 5, 1945, Southern District of Iowa.

ALLEGED SHIPMENT: From La Harpe, Ill., by the La Harpe Creamery Co. The product was shipped on or about September 3, 1945, and the circulars were shipped during the summer of 1944.

PRODUCT: 8 50-pound pails, 2 barrels, and 11 kegs of *condensed buttermilk emulsion*, and 3 circulars entitled "C. B. E. the Quick Way to Profit," at Burlington, Iowa.

LABEL, IN PART: "C. B. E. (Condensed Buttermilk Emulsions) Analysis Protein, not less than 9.0% [or "Protein, not less than 11.0%"] * * * Ingredients: Condensed Buttermilk, Whey, Wheat Germ, Cod Liver Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the article would be effective to insure healthy, profitable poultry, to increase egg production, and to correct or prevent necro in swine. The article would not be effective for those purposes.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 3, 1946. No claimant having appeared, judgment of condemnation was entered and the product and circulars were ordered destroyed.

1749. Misbranding of Knox-It, Flexo-O Horse Tonic, and Flexo-O Scourene. U. S. v. 502 Cans of Knox-It, 142 Packages of Flexo-O Horse Tonic, and 298 Cans of Flexo-O Scourene. Consent decree of condemnation and destruction. (F. D. C. No. 12892. Sample Nos. 82226-F, 82228-F, 82229-F.)

LIBEL FILED: July 12, 1944, District of New Jersey.

ALLEGED SHIPMENT: On or about April 22 and May 15, 1944, by the Syracuse Pharmacal Co., Inc., from Syracuse, N. Y.

PRODUCT: 502 1-pound cans of *Knox-It*, 142 1¾-pound packages of *Flexo-O Horse Tonic*, and 298 1-pound cans of *Flexo-O Scourene* at Upper Montclair and Singac, N. J.

Analysis showed that the *Knox-It* consisted principally of sulfur, slaked lime, iodides, hexamethylenamine, iodoform, copper sulfate, and plant material including wheat middlings, poke root, and licorice; that the *Flexo-O Horse Tonic* consisted essentially of sodium sulfate, sodium bicarbonate, salt, ferrous

sulfate, and plant material including calumba, juniper, sassafras, ginger, fenugreek, nux vomica, and quassia; and that the *Flexo-O Scourene* consisted essentially of calcium carbonate, with small proportions of the phenolsulfonates of zinc, calcium, and sodium.

NATURE OF CHARGE: *Knox-It*, misbranding, Section 502 (a), the name "Knox-It" and the following statements on the label were false and misleading: "Knox-It For minor disturbances of the mammary system * * * A combination of ingredients which tends to condition milch cows * * * Knox-It also tends to build up the resistance of animals and for this purpose a full tablespoonful may be given daily or oftener, to each animal a week or ten days before calving." The name and the statements quoted represented and suggested that the article would be effective in the treatment of disturbances of the mammary system of cattle; and that it would be effective to build up resistance of animals and to prevent any disturbance of the mammary system. The article would not be effective for such purposes.

Flexo-O Horse Tonic, misbranding, Section 502 (a), the name "Horse Tonic" and the following statements on the label were false and misleading: "Horse Tonic. A general tonic * * * tending to restore vigor in horses that show unthriftiness and are in run-down condition. Useful as a spring tonic and in recurrent colic due to indigestion. It has * * * ingredients which * * * sustain the appetite." The name and the statements quoted represented and suggested that the article would be effective as a tonic for horses and as a general tonic; that it would be effective to restore vigor to horses that show unthriftiness and are in run-down condition; that it would be effective in the treatment of recurrent colic due to indigestion; and that it would be effective to sustain the appetite. The article would not be effective for such purposes. Further misbranding, Section 502 (a), the label statement, "iron sulfate, dried (Fe 98%)," was false and misleading since neither the article nor dried iron sulfate contain 98% of iron; and, Section 502 (e), the label failed to bear the common or usual name of each active ingredient since it failed to reveal the presence of sodium sulfate and did not bear the common name of any official drug containing sodium sulfate as an ingredient.

Flexo-O Scourene, misbranding, Section 502 (a), the name "Scourene" and the following statements on the label were false and misleading: "Scourene An Astringent Medication For Intestinal Derangement In Farm and Dairy Animals * * * For Intestinal Infections Shown by Simple Diarrhoea in Farm Animals * * * These ingredients are astringents and have long been used as a corrective medicine in simple scours in calves, colts, pigs, dogs, and lambs and where such contagion exists among fowls. * * * Give Scourene only when needed and only as long as needed." The name and the statements quoted represented and suggested that the article would be effective for scours of farm animals; that it would be effective as an astringent medication for intestinal disturbances of farm and dairy animals; and that it would be effective for intestinal infections and simple diarrhea in farm animals. The article would not be effective for such purposes.

DISPOSITION: February 5, 1946. The consignee of the products having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered destroyed.

DRUG ACTIONABLE BECAUSE OF DECEPTIVE PACKAGING

1750. Misbranding of cough drops. U. S. v. 80 Boxes of Cough Drops. Default decree of condemnation. Product ordered delivered to charitable institutions. (F. D. C. No. 19175. Sample No. 7936-H.)

LIBEL FILED: On or about February 11, 1946, District of Connecticut.

ALLEGED SHIPMENT: On or about January 7, 1946, by Cocilana, Inc., from Brooklyn, N. Y.

PRODUCT: 80 boxes, each containing 26 packages, of *cough drops* at Stamford, Conn. Examination showed that the packages of the product were slack-filled in that each contained 24 cough drops, whereas there was sufficient space for an additional 6 cough drops in the package.

LABEL, IN PART: (Packages) "Cocilana Cough-Nips 'Original' Net Weight 2 Ounces."

NATURE OF CHARGE: Misbranding, Section 502 (i) (1), the container of the article was so filled as to be misleading since an additional 6 cough drops could be placed in each package.

DISPOSITION: March 21, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to charitable institutions.

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¹ Prosecution contested.

² (1744) Seizure contested.

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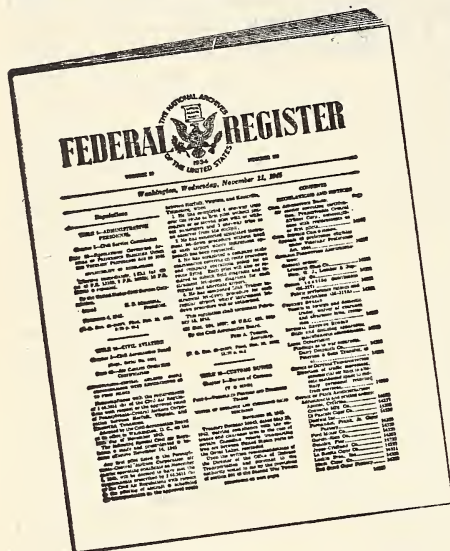
¹ Prosecution contested.

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² Seizure contested.

FEDERAL REGISTER

Official Daily Service



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